

### **2024** Women-Owned Small Business Fair

Hosted by the U.S. Food and Drug Administration





# Welcome & Opening Remarks

Leonard Grant Head of Contracting Activity Food & Drug Administration

### HCA Welcome

- 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; FY23 we met our SB goals except for WOSB & SDVOSB; Greater effort in FY24
- FDA host 2 Small Business Vendor Fairs in FY24 [1 general SB and 1 specific]
- Updated FDA's Procurement Forecast was recently 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 (Cynthia Anderson) to support access to federal contracting opportunities within the FDA
  - HHS OSDBU Small Business Customer Experience (SBCX) https://osdbu.hhs.gov/
  - Actions go through our Small Business Specialist, Cindy Anderson, and if necessary, SBA PCR for review and concurrence
- Take advantage of this virtual event and the opportunities provided to understand our mission, meet, and network with the attending FDA staff (to include Contracting, Program)



Shannon Jackson Sharmon C Jackson Executive Director Office of Small and Disadvantaged Business Utilization (OSDBU)

FDA Small Business Goals for Fiscal Year (FY) 2024

January 19, 2024

### FDA FY2024 Small Business Goal

				ABORATORY	
FO	OD AND DRU	G ADMINIST	RATION		

As you are aware, small businesses are critical to our nation's economic strength and their success is dependent upon our collaborative efforts. To that end, this memorandum presents the assigned small business goals for Fiscal Year (FY) 2024 for the Food & Drug Administration (FDA). For FY 2024, FDA's small business prime contracting goal of 33.06% represents the maximum practicable opportunity for small business to participate in providing the requisite goods and services in support of the mission of FDA. Jeators considered in determining these goals included an analysis of FDA's historical spending and a three-year small business goal achievement (FY2021+FY2023) analysis. The achievement of your assigned small business goals, as presented below, will assist the Department in achieving its small business goal of 23%.

FY 2024 FDA Small Business Goals	Small Business (SB)	Small Disadvantaged Business (SDB)	Women-Owned Small Business (WOSB)	Service-Disabled Veteran Owned Small Business (SDVOSB)	Historically Underutilized Business Zone Small Business (HUBZone)
Prime Contracting	33.06%	26.50%	9.00%	4.41%	4.34%

Section 501 of Public Law 100-656 requires executive agencies to prepare an annual forecast of expected contract opportunities that small business concerns are capable of performing. Please ensure that your OPDIV's forecast of contract opportunities is uploaded into the HHS OSDBU Small Business Customer Experience (SBCX) Opportunities Forecast located at <u>https://odub.tht.gov</u>. Update as necessary, but at a minimum, at least quarterly.

Please review Acquisition Alert 2014-01, Annual Procurement Forecast Guidance, and the Deputy Secretary Memorandum Issued on June 24, 2022, on the Utilization of Small Businesses in Support of the HHS Mission for additional information on this requirement.

Small businesses are critical team members and are vital for advancing the HHS mission 5.0, thank you for your commitment to our nators' small business community. Your continued support in promoting small business participation in FDA's procurement portfolio is greatly appreciated. I look forward to our ongoing collaboration and maximizing opportunities for multi businesses in support of the HHS mission priorities.

Please contact Shannon Jackson, Executive Director, Office of Small and Disadvantaged Business Utilization with any questions at <u>Shannon.Jackson@hhs.gov</u>.

#### As of 5-14-24

FROM:

DATE:

SUBJECT:

FDA (7524)												
OPDIV/STAFFDIV	Total Proc	urement	SB		SDB		WOSB		HZ		SDVOSB	
Goals	Estimated FY Goal	\$1,962,471,134	33.06%	\$648,792,957	26.50%	\$520,054,851	0.000/	\$176,622,402	4.34%	\$85,171,247	4.41%	\$86,544,977
Guais	YTD Goal		0700,002	\$210,912,101	20,2070	\$169,061,424	9.00%	\$57,417,087		\$27,687,795		\$28,134,373
Achievements	YTD Actual	\$637,967,637	46.88%	\$299,109,795	30.84%	\$196,749,617	12.16%	\$77,606,801	5.90%	\$37,644,835	6.35%	\$40,520,049

### OAGS Contact Information FDA

- Ron Loube, Associate Director, 240-402-7539 / ronald.loube@fda.hhs.gov
- Andrew Jernell, Acting Senior Acquisition Advisor, 240-402-0742 / andrew.jernell@fda.hhs.gov
- Sandy Bellinger, Director, Division of Acquisition Programs (DAP) [Facilities and Lab Support/Services/Supplies] 240-402-7524 / 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
- Vidya Vish, Director, Division of Acquisition Operations (DAO) [Professional Services, Training, Research (BAA)] 240-402-7576 / vidya.vish@fda.hhs.gov
- Phillip Frame, Acting Director, Division of Information Technology Acquisitions (DITA) [All IT] 240-402-7578 / Phillip.Frame@fda.hhs.gov
- Bryan Jones, Director, Division of Systems, Policy, and Program Support (DPSPS) 240-402-7571 / bryan.jones@fda.hhs.gov





### Office of Acquisition 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 FDA Mission 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, sciencebased 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.

### What Does FDA Regulate FDA



- Foods, including:
  - dietary supplements
  - bottled water
  - food additives
  - infant formulas
  - other food products (although the U.S. Department of Agriculture plays a lead role in regulating aspects of some meat, poultry, and egg products)
- Drugs, including:
  - prescription drugs (both brand-name and generic)
  - non-prescription (over-the-counter) drugs
- Biologics, including:
  - vaccines for humans
  - blood and blood products
  - cellular and gene therapy products
  - tissue and tissue products
  - allergenics
- Medical Devices, including:
  - simple items like tongue depressors and bedpans
  - complex technologies such as heart pacemakers
  - dental devices
  - surgical implants and prosthetics
- Veterinary Products, including:
  - livestock feeds
  - pet foods
  - veterinary drugs and devices





### What Does FDA Regulate





#### • Electronic Products that give off radiation, including:

- microwave ovens
- x-ray equipment
- laser products
- ultrasonic therapy equipment
- mercury vapor lamps
- sunlamps

#### Cosmetics, including:

- color additives found in makeup and other personal care products
- skin moisturizers and cleansers
- nail polish and perfume

#### Tobacco Products, including:

- cigarettes
- cigarette tobacco
- roll-your-own tobacco
- smokeless tobacco
- Cigars
- Hookah
- E-cigarettes (tobacco and non-tobacco derived nicotine)







### **FDA Centers and Offices (Our Stakeholders)**





**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 Digital Transformation (ODT) 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 FDA.gov

### **Commodities and Services FDA**

- **Research Studies**
- □ Investigations, surveys
- □ Test and analysis of a scientific or medical nature
- □ Inspections and Compliance reviews
- Professional Services
- □ Administrative Support/Temporary Services
- □ Conference Support/Event Planning
- Document Management
- Training
- □ Facilities renovation
- □ Architect/Engineering Support
- Operation and Maintenance of Facilities
- □ Facilities Support (e.g. custodial, trash, guard services)
- □ Moving Services

https://www.fda.gov/about-fda/what-we-do

#### **Commodities and Services Continued...**



- □ 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.)

### OAGS Mission, Vision, & Goals

Mission

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



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.



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

#### How We are Organized



#### Innovation, Systems & Data Quality Branch

Provides system support and serves as the PRISM, UFMS, FPDS, ALP and AAP focal point for OAGS. Tracks and analyze acquisition data, performs audits of acquisition actions, and supports program acquisition needs. Looks for innovative ways to promote office efficiency and effectiveness. Purchase Card Audit and Administration Program

Grants and Assistance Agreements Branch Negotiate, award and monitor federal funds awarded through various grant mechanisms.

#### CTP Contracts Branch

Contracts to support the compliance and enforcement of The Family Smoking Prevention and Tobacco Control Act (TCA). Contracts with states, territories, private contractors and tribal governments, to conduct compliance check inspections of tobacco product retailers

#### **ORA 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

#### **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 Information Technology Branches (IT Acquisitions, Strategic Support & Systems Technology) All information technology related contracts and simplified acquisitions

#### **Service Contracts 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.

#### **Contract Admin Branch**

Serves as a central support function for contract administration of all transactions from the time the contract is awarded through closeout. Has the responsibility of tracking and processing invoices. Serves as the conduit for the preparation, processing, coordination, execution, administration, and close-out of Interagency Agreements (IAAs), which ae currently phasing out. G-Invoicing is now being implemented in its place.

#### Training & Development Branch

Provides training and developmental courses to promote staff growth and development. Conducts specialized training for entry level Contracts Specialists. Provides Acquisition Career Management overseeing the certification programs, FAC-C (Professional & Digital Services), FAC-COR, FAC-P/PM

#### Scientific Support Branch

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

OAGS

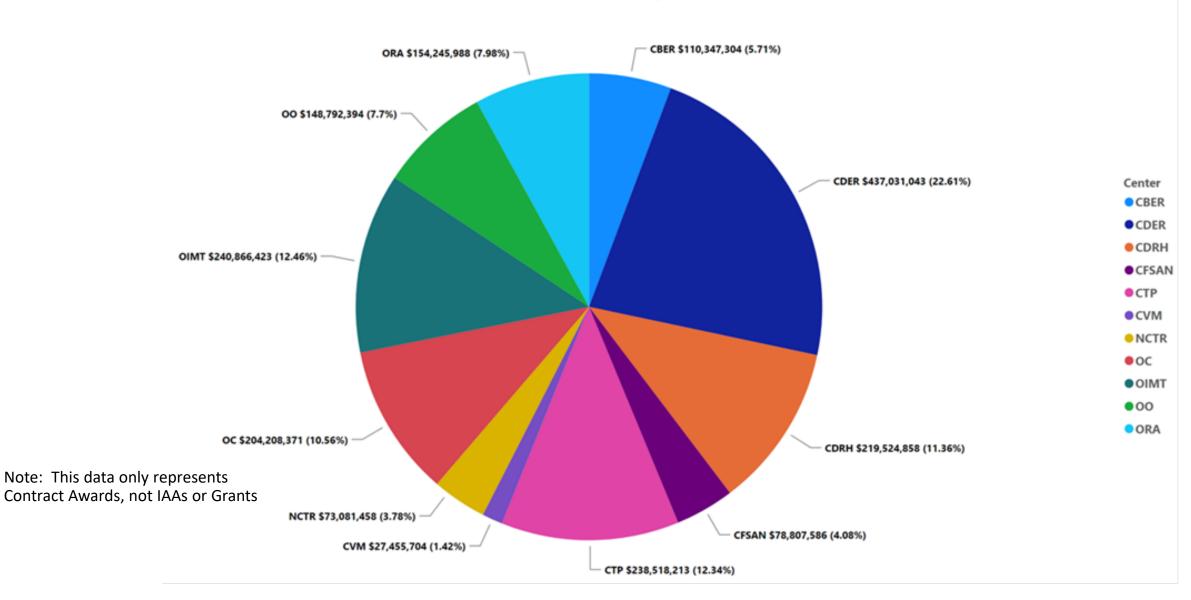
### FDA OAGS Website



- Learn more about OAGS here: Doing Business With FDA | FDA
  - OAGS Points of Contact
  - Forecast Link
  - FDA eBid Board: an electronic portal designed to promote awareness of and competition in business opportunities for contract actions with an anticipated value between \$15,001 \$25,000.
  - Vendor Payment FAQs
  - Past Small Business Events Information
  - Grants Information

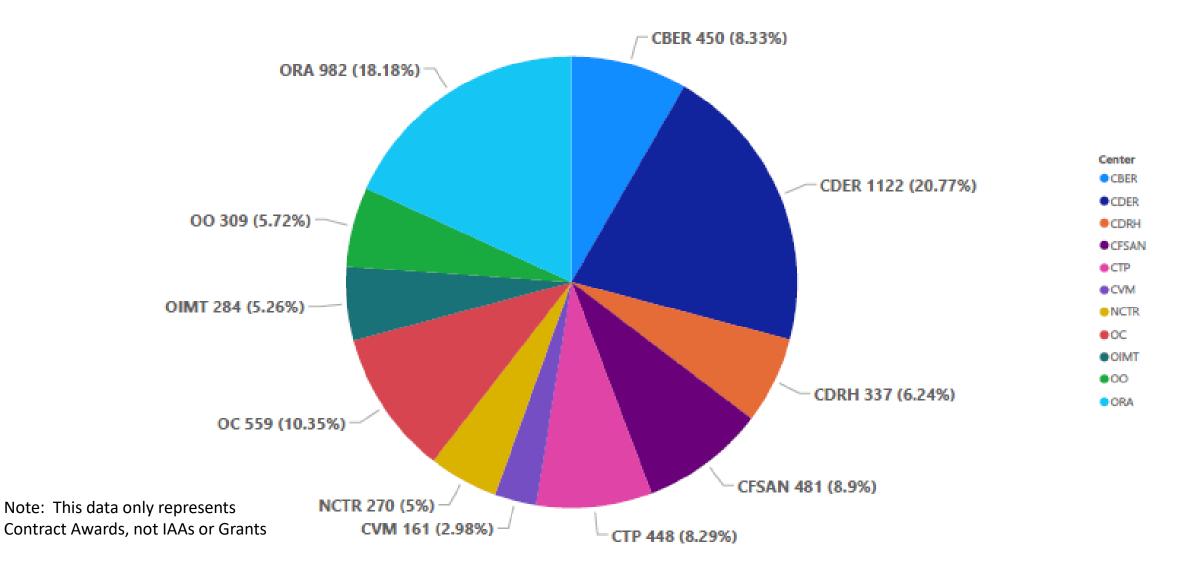
#### **FY23 Statistics for OAGS**

#### Action Dollars by Center



#### **FY23 Statistics for OAGS**

#### Action Count by Center



#### **FDA Socioeconomic Goals**

Small Business Award Categories	FY Goal (FY15-21)	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23 Goal	FY23
Small Businesses	38%	48.50%	39.64%	36.80%	39.06%	40.09%	34.33%	33.49%	37.09%	38.02%
Small Disadvantaged Businesses	5.00%	27.90%	24.31%	25.00%	27.14%	26.96%	23.84%	23.96%	25.20%	25.84%
Women-Owned Small Businesses	5.00%	17.80%	14.22%	14.10%	14.13%	12.68%	10.33%	11.01%	11.99%	11.58%
HubZone Businesses	3.00%	2.00%	1.40%	1.80%	2.75%	4.09%	3.81%	4.48%	4.94%	4.37%
Service-Disabled Veteran Owned	3.00%	4.90%	3.42%	3.40%	2.81%	3.91%	2.29%	3.22%	3.80%	3.79%

In 2023, FDA awarded more than \$755 Million to Small Businesses!

### Top 10 Contract Expenditure Categories for FY 2023 FDA

#### Top 10 Vendors

Vendor Name	Su	m of Dollars Obligated
DELOITTE CONSULTING LLP	\$	144,858,874.83
BOOZ ALLEN HAMILTON INC.	\$	130,818,922.77
TRUE NORTH COMMUNICATIONS INC.	\$	95,800,000.00
REI SYSTEMS, INC.	\$	47,124,299.11
AMERIND BG JV, LLC	\$	43,333,253.00
PERSPECTA ENTERPRISE SOLUTIONS LLC	\$	41,716,356.77
HARVARD PILGRIM HEALTH CARE INC	\$	39,292,974.85
INTERNATIONAL BUSINESS MACHINES CORPORATION	\$	35,401,037.25
EAGLE HILL CONSULTING, LLC	\$	34,663,336.19
PRECISE SOFTWARE SOLUTIONS, INC.	\$	34,316,436.40
Grand Total	\$	647,325,491.17

#### Top 10 NAICS

Top 10 NAICS by Expenditures	Sı	um 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 NANOBIOTECHNOLOGY) – 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 FY2023

#### **Top 10 Small Business Vendors**

Top 10 SB Contract Expenditures	Sı	um of Dollars Obligated
AMERIND BG JV, LLC	\$	43,333,253.00
PRECISE SOFTWARE SOLUTIONS, INC.	\$	34,316,436.40
MPF-ZAI SOLUTIONS, LLC	\$	33,788,070.98
BRILLIENT CORPORATION	\$	31,152,710.77
INTERNATIONAL CONSULTING ASSOCIATES INC	\$	19,004,078.64
SPATIAL FRONT INCORPORATED	\$	14,447,558.74
PN-HEITECH, LLC	\$	13,915,653.22
EQUINOXYS INC.	\$	12,214,944.23
SOFTWARE INFORMATION RESOURCE CORP.	\$	11,117,085.65
SUNTIVA, LLC	\$	11,056,093.63
Grand Total	\$	224,345,885.26

#### **Top 10 Small Business NAICS**

Top 10 NAICS (Small Business Contracts)	Sun	n of Dollars Obligated
COMPUTER SYSTEMS DESIGN SERVICES - 541512	\$	102,433,722.87
ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES – 541611	\$	95,490,716.46
OTHER COMPUTER RELATED SERVICES – 541519	\$	89,271,534.67
CUSTOM COMPUTER PROGRAMMING SERVICES – 541511	\$	69,595,359.04
ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES – 541990	\$	60,115,010.62
COMMERCIAL AND INSTITUTIONAL BUILDING CONSTRUCTION – 236220	\$	52,698,622.00
COMPUTER FACILITIES MANAGEMENT SERVICES – 541513	\$	21,632,974.93
FACILITIES SUPPORT SERVICES – 561210	\$	18,105,882.52
RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY (EXCEPT NANOBIOTECHNOLOGY) – 541714	\$	14,940,622.25
OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES – 541690	\$	8,439,252.31
Grand Total	\$	532,723,697.67

## Top 10 Women-Owned Small Businesses by Dollars for FDA FDA FDA

Top 10 WOSB Contract Expenditures	Sum of Dollars Obligated
Spatial Front Inc.	\$14M
MPF-ZAI Solutions LLC	\$10M
Software Information Resource Corp	\$10M
Avcor Construction	\$9M
FCN Inc.	\$6M
A-Tek Inc.	\$6M
Chags Health Information Technology LLC	\$6M
AC Integrity Partners LLC	\$4M
Ivyhill Technologies LLC	\$4M
Tyrula LLC	\$3M
Grand Total	\$72M

### Women-Owned Business Awardees by Dollars for FY 202

Category	Dollars Awarded	Contracts Awarded
Women-Owned (WO)	\$ 141,764,564	167
Women-Owned Small Business (WOSB)	\$ 103,895,991	125
Economically Disadvantaged Women-Owned Small Business (EDWOSB)	\$ 63,339,896	81
Total	\$ 309,000,451	373

#### Sources for Women-Owned Small Business Awards for FDA FY 2023

Acquisition Vehicles	Dollars Awarded
Existing FDA Vehicles	\$40M
NASA SEWP	\$21M
FAS/GSA	\$11M
NIH/NITAAC	\$9M
Total	\$81M
Open Market	\$24M

Tip: Get on an Acquisition Vehicle!



### **Are You Procurement Ready?**



Procurement ready means have you done your homework? Do you have capabilities the FDA is seeking (including past performance) and have you done the necessary research to be successful?

- □ Are you registered in the System for Award Management (SAM.gov)?
- □ Have you confirmed that FDA buys what you sell/perform?
- □ Have you reviewed each FDA Center's mission/responsibilities?
- Have you registered your company in the HHS Small Business Customer Experience Portal (SBCX)?
- □ Have you uploaded your capability statement to SBCX? Is your SBCX profile complete?
- □ Have you searched for HHS Opportunities on the forecast posted on SBCX?
- □ Have you prepared your <u>5-Slide Capability Briefing</u>?
- □ Have you reached out to FDA's SB Specialist/Requiring Office POC from the forecast?
- □ Have you attended an HHS or FDA outreach event to meet decision makers?
- □ Have you positioned your company on a GSA Schedule, GWAC, BIC tool?
- Do you have strategic partnerships with other SBs or LBs (i.e. JVs, MPAs)?
- □ Have you obtained certifications that are critical to your success?

### Best Practices for Doing Business with FDA

#### Target your Engagement

- Focus on Primary NAICS codes and consider teaming/partnering
- Learn about FDA market and the goods and services it procures
- Get on an Acquisition Vehicle

#### **Develop Allies**

- Engage with <u>FDA SB Specialist</u>
- Participate in FDA and HHS <u>outreach events</u>

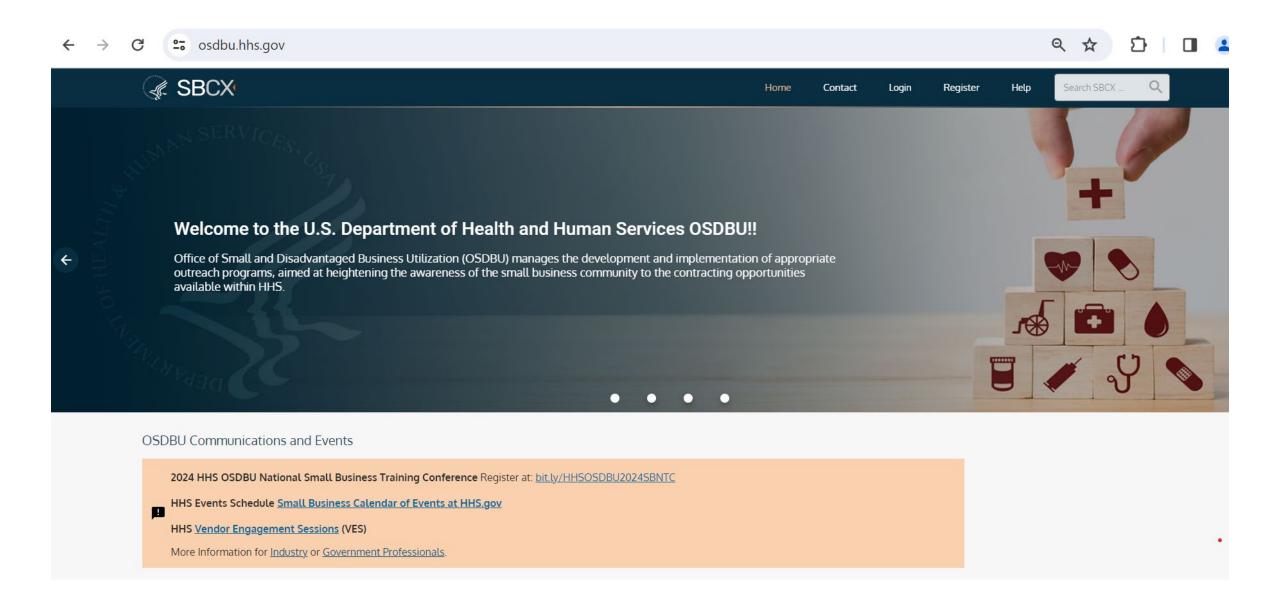
#### **Own Your Future**

- Be Procurement Ready
- Review FDA Forecast of Opportunities
- Understand how to write a <u>Capability Statement</u> and perform a Capability Briefing
- Know the Rules (FAR and GAO Case Law-Protest Decisions)

#### **Best Practices, continued FDA**



#### HHS Small Business Customer Experience (SBCX) FDA



### SBCX Forecast FDA

SBCX	Home	Contact	Login	Register	Help	Search SBCX	Q
Event Name	Date						
Get Ready for Procurement Opportunities With (G.R.O.W) HHS Session	Tuesday, March 5, 202	t.					
Service-Disabled Veteran Owned Small Business (SDVOSB) Industry Day	Monday, March 11, 20	4					
March 12, 2024 Vendor Engagement Session (VES)	Tuesday, March 12, 20	24					
See all OSDBU Events							
Search Small Business Directory							
Locate small businesses for procurement opportunities.							
Search by keywords, NAICS, company name, UEI				Q			
Search All HHS Opportunities							
Search by title, NAICS, and operating division.							
Search by title, NAICS, and operating division				Q			

### FDA Opportunities FDA

Carl SBCX		OSEM/OSO - Mission-Critical Su	bject Matter Expertise & Administrative S	8	Register	Help Search SBC	( Q
		upport					
Search Opportunities							
FDA		programs. OSO ensures a secure and safe work	nel to support the FDA/OSEM/Office of Security Operations' se cplace for all employees, contractors and visitors, as well as ograms: Personnel Security, Physical Security, Foreign Visitor				
		Show More •••					
541611 Q	Clear Filters	Status	Published				Export
		Anticipated Acquisition Strategy	To be determined			_	
Title	Primary NAICS	Primary NAICS	541611 : Administrative Management and General Management Consulting Services			Program Office POC First Name	Actions
Ŧ		Total Contract Range	>= \$1.5M and < \$3M		÷		
	_	Target Solicitation Month/Year	1 / 2024				
OC OGPS Organizational	541611 : Adm	Target Award Month/Year (Award by)	8 / 2024			RAFFAELE	:
Excellence Support- Base Year		Operating Division	FDA				
Executive Leadership Retreats for	541611 : Adm	Program Office POC Name	JAMES FREE			ASHLEY	:
Change Management		Program Office POC Email	JAMES.FREE@fda.hhs.gov				
OSEM/OSO - Mission-Critical	541611 : Adm	Program POC Office	75F401: FDA OFFICE OF ACQ GRANT SVCS			JAMES	:
Subject Matter Expertise &		Contracting Office	75F401: FDA OFFICE OF ACQ GRANT SVCS				
Administrative Support		CO Name	TBD TBD				
		CO Email	TBD@fda.hhs.gov				
		Incumbent Contractor (if applicable)	Not Provided				
		Existing Contract number (if applicable)	Not Provided	-			
↓ →	•	4		•			

#### New Small Business Customer Experience (SBCX) FDA Teaming Partner Portal

#### LAUNCHED IN APRIL

Designed to further facilitate collaboration and partnership opportunities for small businesses.

The SBCX Teaming Partner Portal feature offers:

- SBCX Prime Business (OTSB or SB) users the ability to publish teaming opportunities tailored to target small business partners, by socio-economic category, NAICS, and keywords.
- Prime business users can efficiently manage responses, make notes, and select preferred partners for collaboration.
- It allows small business users of SBCX the ability to view new opportunities in a public dashboard, to easily track Teaming Opportunities they've been personally invited to, and the ability to respond to those invitations.

Visit osdbu.hhs.gov for more information



### OAGS Contracting Officer Panel

Thank you for submitting your questions during Registration.



### **Panel Introductions**

Kim Davis, DAO Ian Weiss, DAO Jay O'Keefe, OD-Training Sheneil Greene, DAP Phillip Frame, DITA

### **OAGS Panel Questions** FDA

Question: How does the FDA collect the information for the Forecast of Opportunities? Where is this information posted? How often is this information updated? What are your Forecast Opportunities in the 4th Quarter for WOSB companies?

Question: How open is FDA to working with woman-owned small businesses or small businesses that are not currently working at FDA?

**Question:** How can small businesses learn about opportunities that are under \$25,000?

#### **OAGS Panel Questions** FDA

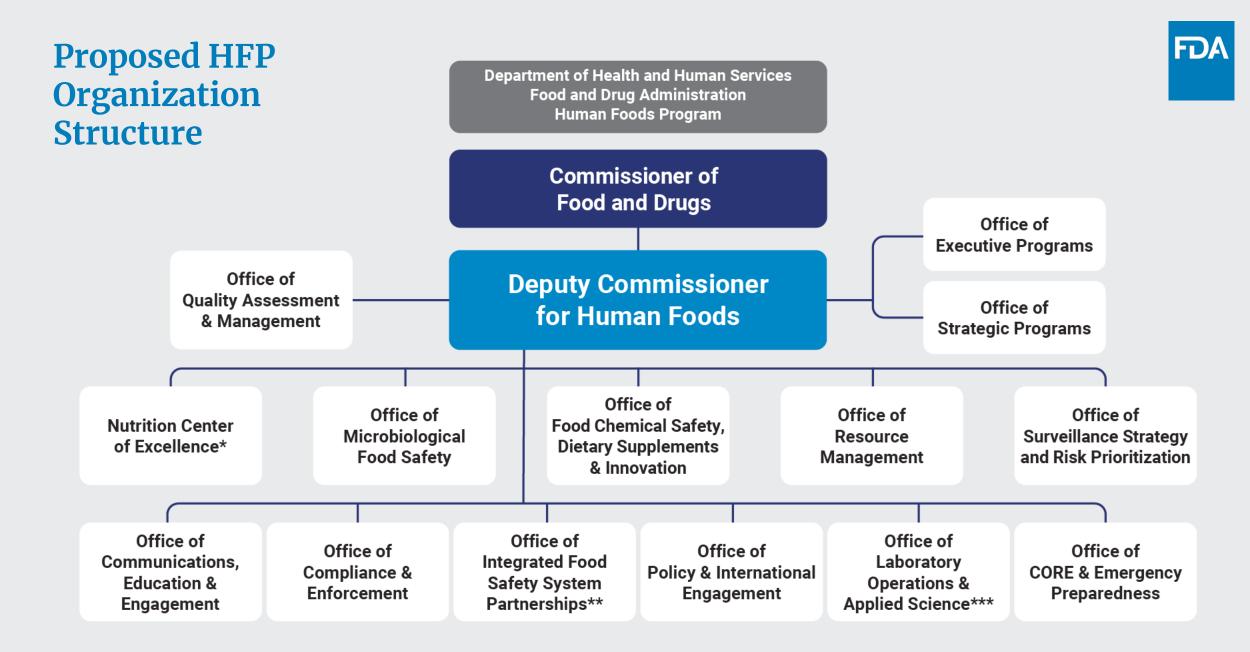
- Question: When is the best time to reach out for capabilities briefings? How to schedule capability meetings?
- **Question:** What are unique attributes about FDA procurement practices that contractors should know?
- **Question:** What research opportunities are available for WOSBs?



#### Question: How has the utilization of Best-in-Class, GWACs, and Category Management impacted Information Technology procurements at FDA?

**Question:** What are your tips for successful matchmaking?

Question: What is the most important thing that a WOSB must do to compete effectively for business from FDA?



\*Includes Office of Critical Foods

\*\*OIFSSP will work in close coordination with the Center for Veterinary Medicine

\*\*\*OLOAS will work in close coordination with the Office of the Chief Scientist and Center for Veterinary Medicine

Note: The proposed changes reflected here are not approved and will not be implemented until all required reorganization steps have been met.



### Unified HFP Functional Model

### **Risk management functions**

managing public health risks through 3 areas of focus:

• nutrition; microbiological food safety; and chemical safety

### **Strategic management functions**

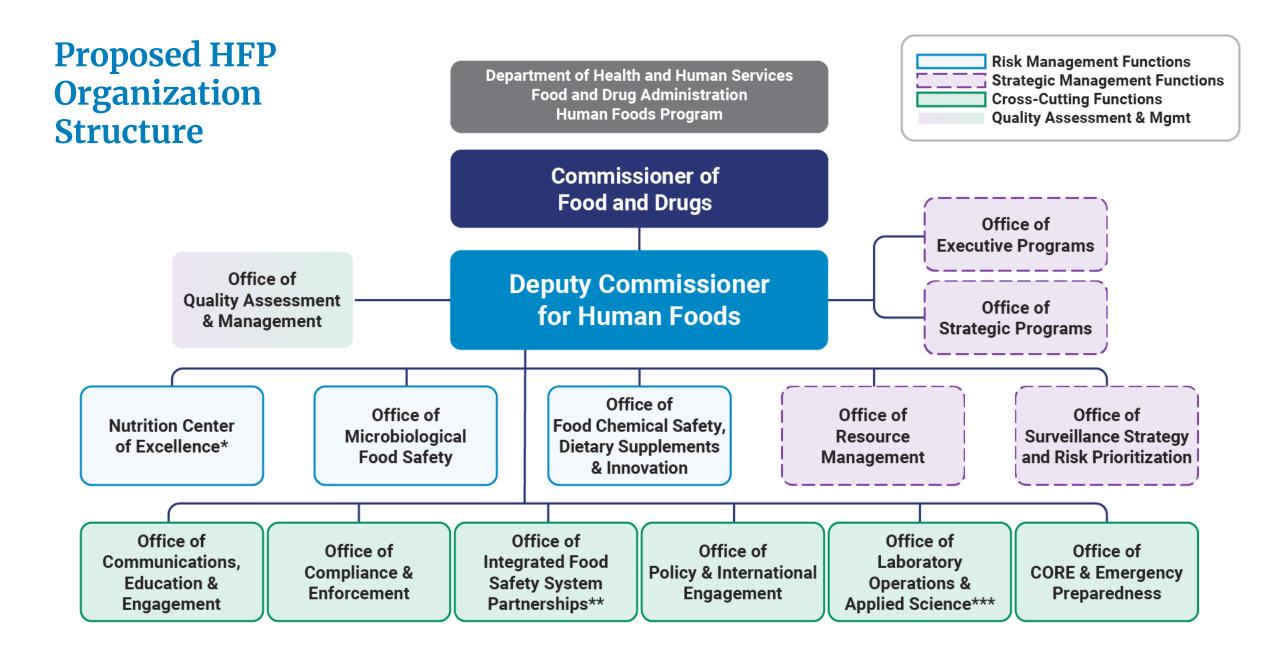
leveraging data to better prioritize activities and resources based on risk

 surveillance strategy; risk-informed decision framework; and resource management for HFP and related field activities

### **Cross-cutting functions**

the "tools" supporting risk management priorities

 integrated food safety system partnerships; laboratory operations and applied science; compliance and enforcement; policy; and communications and engagement



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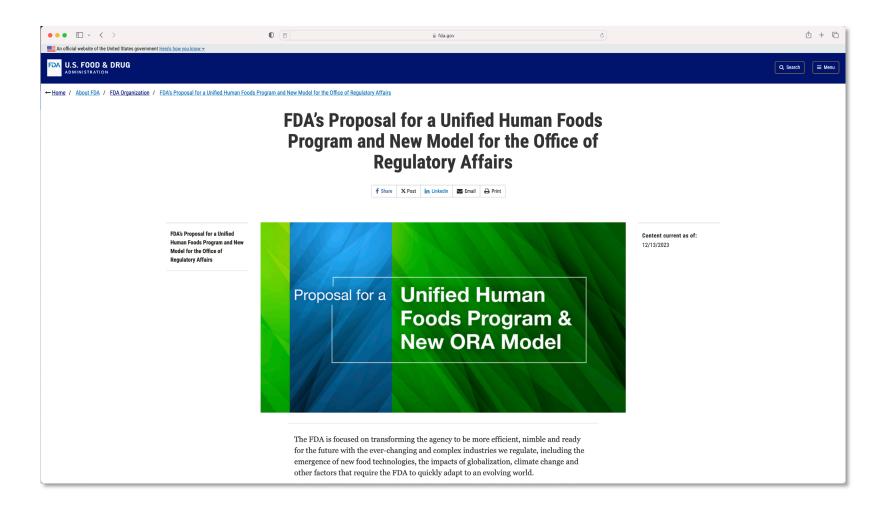


## **Timeline for the Proposed FDA Reorganization**





### For More Information



## Center for Biologic Evaluation and Research (CBER) Overview

Presented by: Lisa Portner, Branch Chief & Niquwana Bullock, Sr. Program Analyst

## Center Overview - Center Location



Buildings 51\*, 52/72, 71, and 75



Building 71- Leadership and Administrative



Building 52/72- Lab Activity



Building 75- HIVE

\*Building 51 houses WOC-AP Vivarium and is located under Buildings 52/72

## CBER Overview – CBER Strategic Plan

Goal 1: Facilitate the development and availability of safe and effective medical products through the integration of advances in science and technology

Goal 2: Conduct research to address challenges in the development and regulatory evaluation of medical products

Goal 3: Increase preparedness for emerging threats and promote global public health

Goal 4: Manage for strategic excellence and organizational accountability

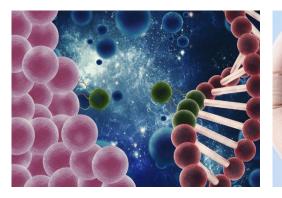
## Role of a Regulatory Agency

*Definition:* A regulatory agency, such as the FDA, is responsible for exercising complete authority over some area of human activity in a regulatory capacity (restricting according to rules or principles).

• FDA regulates \$1 trillion worth of products a year, approximately \$0.24 of every dollar spent in the U.S.



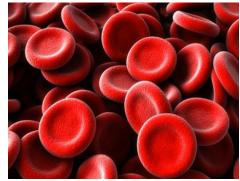
## **CBER Regulates Complex Products**



Cell & Gene



Vaccines: Preventive & Therapeutic



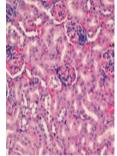


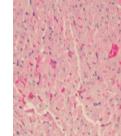






Related Devices Allergenic Products Biotherapeutics Tissues





### ACQUISITION STRATEGIES

- Strategic Sourcing/Category Management
- GSA Federal Supply Schedules (FSS)
- Government Wide Acquisition Contracts (8(a) STARS II, CIOSP3 (SB), Alliant SB, NASA SEWP)
- Open Market
  - Indefinite delivery/indefinite quantity vehicles
  - Contracts
  - Purchase orders

## What We Buy

B

R

General/Science Support Services	<ul> <li>Scientific Support Services (i.e. Lab Technician, Animal Care Technicians, etc.)</li> <li>Sequencing Services</li> <li>Consultation Services</li> <li>Executive Coaching</li> </ul>
Scientific Equipment	<ul> <li>Mass Spectrometers</li> <li>Cytometers</li> <li>Advanced Microscopes</li> <li>Sample Storage Ultra Low Freezers</li> </ul>
Information Technology (IT)	<ul> <li>Small System Development</li> <li>Support Services and Consultation</li> </ul>
Scientific Samples	<ul> <li>DNA/RNA Protein Samples</li> <li>Virus/Bacteria Specimen Samples</li> <li>Derivation Samples</li> </ul>
General Laboratory Supplies	<ul> <li>Laboratory Glass Ware (Pipettes, Beakers, Petri dishes, etc.)</li> <li>Safety Products (Latex Gloves, Disposable Lab Coats, etc.)</li> <li>Cleaning Products and Solutions</li> </ul>

## Top 10 Small Business Product Service Codes(PSC) Awarded by CBER

### FY 2024 YTD Small Business New CBER Awards by PSC

Product Service Code Description	Actions Awarded
IT AND TELECOM - BUSINESS APPLICATION SOFTWARE (PERPETUAL LICENSE SOFTWARE) - 7A21	2
LABORATORY EQUIPMENT AND SUPPLIES – 6640	2
MAINT/REPAIR/REBUILD OF EQUIPMENT- INSTRUMENTS AND LABORATORY EQUIPMENT - J066	2
SUPPORT- MANAGEMENT: OTHER - R799	2
FORAGE AND FEED – 8710	1
LIVE ANIMALS, NOT RAISED FOR FOOD – 8820	1
MAINT/REPAIR/REBUILD OF EQUIPMENT- FURNITURE - J071	1
SPECIAL STUDIES/ANALYSIS- SCIENTIFIC DATA - B529	1
SUPPORT- ADMINISTRATIVE: OTHER - R699	1
SUPPORT- PROFESSIONAL: HUMAN RESOURCES - R431	1

### FY 2023 Small Business New CBER Awards by PSC

Product Service Code Description	Actions Awarded
LABORATORY EQUIPMENT AND SUPPLIES - 6640	21
SUPPORT- PROFESSIONAL: OTHER - R499	14
SUPPORT- MANAGEMENT: OTHER - R799	6
IT AND TELECOM – BUSINESS APPLICATION/APPLICATION DEVELOPMENT SUPPORT SERVICES (LABOR) - DA01	4
SUPPORT- PROFESSIONAL: VETERINARY/ANIMAL CARE - R416	4
SPECIAL STUDIES/ANALYSIS- SCIENTIFIC DATA - B529	3
MAINT/REPAIR/REBUILD OF EQUIPMENT- INSTRUMENTS AND LABORATORY EQUIPMENT - J066	2
IT AND TELECOM - APPLICATION DEVELOPMENT SOFTWARE (PERPETUAL LICENSE SOFTWARE) - 7A20	2
SUPPORT- ADMINISTRATIVE: TRANSLATION AND INTERPRETING - R608	2
SUPPORT- PROFESSIONAL: HUMAN RESOURCES - R431	2

### FY 2022 Small Business New CBER Awards by PSC

Product Service Code Description	Actions Awarded
LABORATORY EQUIPMENT AND SUPPLIES – 6640	26
MAINT/REPAIR/REBUILD OF EQUIPMENT- INSTRUMENTS AND LABORATORY EQUIPMENT - J066	8
SUPPORT- PROFESSIONAL: OTHER - R499	8
SUPPORT- MANAGEMENT: OTHER - R799	6
SPECIAL STUDIES/ANALYSIS- SCIENTIFIC DATA - B529	5
IT AND TELECOM - BUSINESS APPLICATION SOFTWARE (PERPETUAL LICENSE SOFTWARE) - 7A21	3
IT AND TELECOM - APPLICATION DEVELOPMENT SOFTWARE (PERPETUAL LICENSE SOFTWARE) - 7A20	2
SPECIAL STUDIES/ANALYSIS- OTHER - B599	2
SUPPORT- PROFESSIONAL: OPERATIONS RESEARCH/QUANTITATIVE ANALYSIS - R405	2
CHEMICAL ANALYSIS INSTRUMENTS - 6630	1



B

D

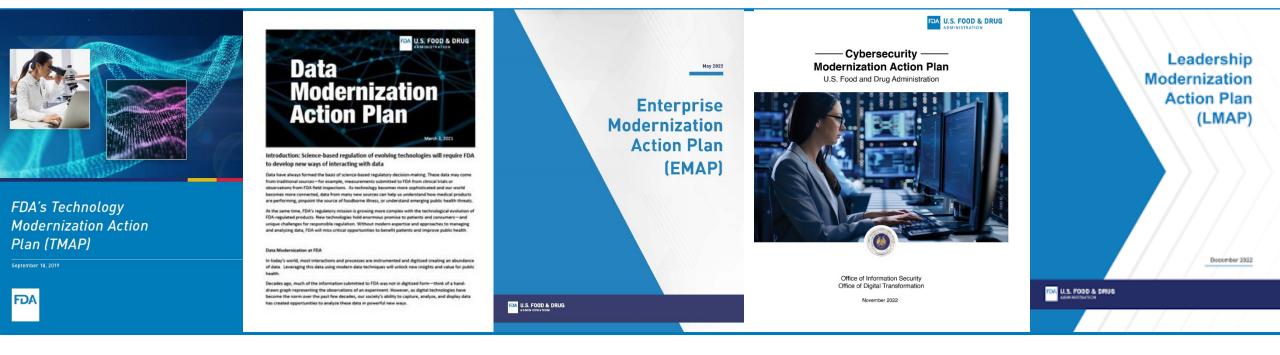




## Office of Digital Transformation

Mahesh Choksi Director, Acquisition Strategies and Partnership Division

## **Our Journey**

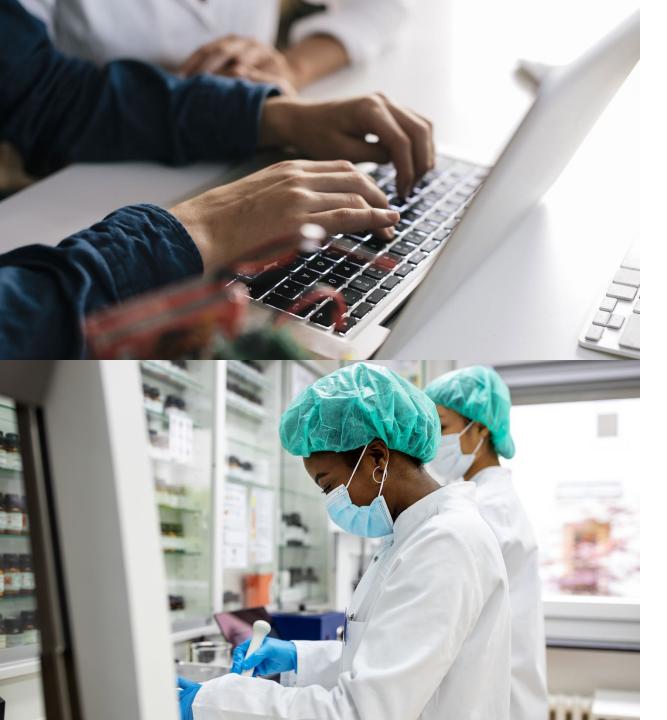


2019



2022

FDA



### **ODT Mission**

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

## **ODT Vision**

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

## **ODT Core Values**

- Accountability
- Empowerment
- Effective Execution

## Challenges

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



**G** 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

## Goals

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 Roadmap





# Our Strategy and Operating Plans are living documents.

We'll keep listening to our stakeholders and integrating their feedback every year.





## We have tough tasks ahead.

We'll achieve them as **OneFDA**.

FDA

### **Enterprise IT Acquisition Strategy**

- 1) Created \$15B 10 Years FDA IT acquisition strategy in 2024 to meet the goals of OneFDA
- 2) Purpose
  - Expand sharing of FDA-wide buying data, leading to better-informed business decisions.
  - Maximize FDA's shared purchasing power, allowing FDA to leverage volume discounts
  - Help FDA operate more efficiently by reducing administrative costs and contract duplication
  - Socio-economic goals alignment
  - Governance and oversight

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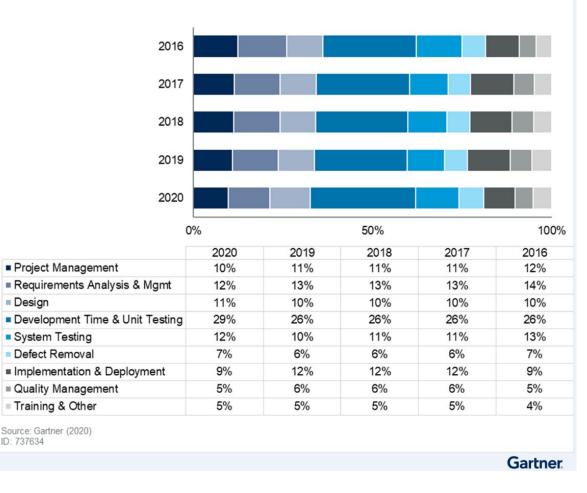
## **Expectations**

Design

ID: 737634

- Be a Strategic Partner and not a billing partner
- Collaborate to achieve FDA Mission and be innovative
- Cooperate with Standard language
  - Weekly Status and monthly **Financial Reporting**
  - Resource Management
  - Place of Performance hybrid work environment
  - Cloud Migration
  - > O&M Cost Reduction
- > Check your spending

Application Development Lifecycle



### Most used PSC codes for FDA IT

### FDA-Wide TOP 10 FY22-FY23 IT PSC Codes

Product or Service Code	PSC Description	FDA-Wide IT PSC - FY22	FDA-Wide IT PSC - FY23
R499	SUPPORT- PROFESSIONAL: OTHER	699	536
DA01	IT AND TELECOM - BUSINESS APPLICATION/APPLICATION DEVELOPMENT SUPPORT SERVICES (LABOR)	133	108
DF01	IT AND TELECOM - IT MANAGEMENT SUPPORT SERVICES (LABOR)	107	67
R408	SUPPORT- PROFESSIONAL: PROGRAM MANAGEMENT/SUPPORT	107	58
D318	IT AND TELECOM- INTEGRATED HARDWARE/SOFTWARE/SERVICES SOLUTIONS, PREDOMINANTLY SERVICES	78	20
R699	SUPPORT- ADMINISTRATIVE: OTHER	74	33
R406	SUPPORT- PROFESSIONAL: POLICY REVIEW/DEVELOPMENT	73	58
R410	SUPPORT- PROFESSIONAL: PROGRAM EVALUATION/REVIEW/DEVELOPMENT	66	19
DA10	IT AND TELECOM - BUSINESS APPLICATION/APPLICATION DEVELOPMENT SOFTWARE AS A SERVICE	60	7
J049	MAINT/REPAIR/REBUILD OF EQUIPMENT- MAINTENANCE AND REPAIR SHOP EQUIPMENT	60	7
	Total	1457	913

FDA

### FDA Wide FY22-FY23 IT NAICS Code

NAICS Code	NAICS Description	FDA-Wide NAICS - FY22	FDA-Wide NAICS - FY23
541519	OTHER COMPUTER RELATED SERVICES	12	520
541990	ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	30	386
541511	CUSTOM COMPUTER PROGRAMMING SERVICES	10	265
541611	ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES	115	783
611430	PROFESSIONAL AND MANAGEMENT DEVELOPMENT TRAINING	131	71
518210	DATA PROCESSING, HOSTING, AND RELATED SERVICES	12	127
511210	SOFTWARE PUBLISHERS	299	61
238210	ELECTRICAL CONTRACTORS AND OTHER WIRING INSTALLATION CONTRACTORS	635	6
334111	ELECTRONIC COMPUTER MANUFACTURING	840	40
443120	COMPUTER AND SOFTWARE STORES	497	20
541330	ENGINEERING SERVICES	105	11
	Total	2686	2290

FDA

## **Questions?**



## Delivering WOSB Excellence

U.S. Food and Drug Administration WOSB Fair May 29, 2024





### WHAT IS THE BOW COLLECTIVE?

The BOW Collective is a business development sisterhood of the Nation's top Black Women Owners. We build and scale our businesses, together. The Ladies of the BOW Collective focus on sharing resources and relationships and on the 3Cs of business growth: Capital, Communications and Contracts/Clients.

#### As of 2024:

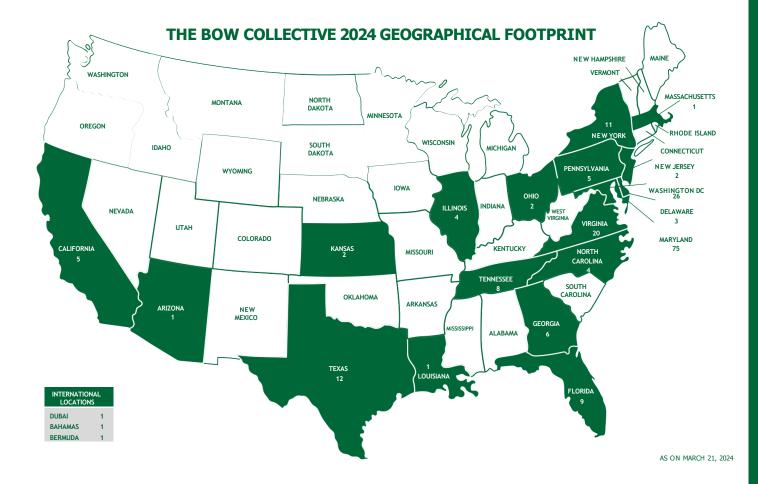


The organization has been featured in media outlets such as **Black Enterprise**, **Enterprising Women**, and the Washington Business Journal for its innovative and collaborative effort.





### WHERE WE ARE LOCATED



### **BOW INDUSTRIES**

- ACCOUNTING
- ARCHITECTURE
- BUSINESS CONSULTING
- CHILDCARE
- CHEMICALS & DISTRIBUTION
- CLEANING & MAINTENANCE
- COMMERCIAL INTERIOR DESIGN
- COMMUNICATIONS
- DIVERSITY & INCLUSION TRAINING
- DENTISTRY
- EVENT MANAGEMENT
- FINANCIAL ADVISORY SERVICES
- GOVERNMENT CONTRACTORS
- HEALTHCARE
- HOSPITALITY
- HUMAN RESOURCES
- INSURANCE
- IT SOLUTIONS
- LEGAL
- LOGISTICS & MOVING
- MANUFACTURING
- MARKETING
- NONPROFITS
- PROJECT & PROGRAM MANAGEMENT
- PERFORMING ARTIST
- PUBLIC RELATIONS
- REAL ESTATE BROKERAGE
- REAL ESTATE CONSTRUCTION & MANAGEMENT
- REAL ESTATE DEVELOPMENT
- RETAIL



### EXECUTIVE BOARD & OFFICERS

The BOW Collective is more than just an organization; it's a dynamic sisterhood and a hub for social capital strategically aligned to elevate the presence of our businesses collectively. Our mission is to create awareness, foster collaboration, and provide a unified platform for our members. Many of our CEOs bring a wealth of experiences from globally recognized professional services organizations, leveraging their industry knowledge to market their products and services effectively. The strength of our collective lies in our unity, collaboration, and the shared commitment to growing our businesses together.

As we embark on this conference journey, let us strengthen our bonds, exchange valuable insights, and collectively work towards a paradigm shift of scaling new heights of success. Thank you for being an integral part of The BOW Collective, where empowerment, growth, and collaboration thrive.





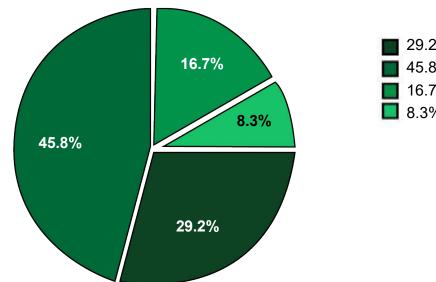


### **ANNUAL REVENUE**

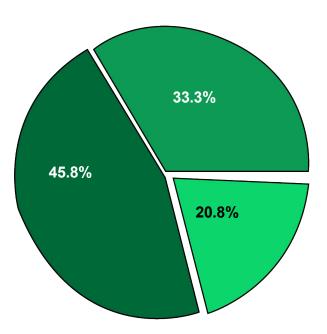
Annual revenue ranges of BOW members in GovCon.



Over 60 percent of the BOW have been successfully supporting Government agencies for more than 5 years.



29.2% Less than \$1M 45.8% \$1M-\$5M 16.7% \$6M-\$10M 8.3% Over \$11M



20.8% Less than 5 years
45.8% 5-10 years
33.3% Over 10 years



### **DEPARTMENTS & AGENCIES**

- U.S. Department of Agriculture
- U.S. Department of Commerce
   National Oceanic and Atmospheric Administration
- U.S. Department of Defense

Air Force

Army Navy

Army Corps of Engineers Defense Logistics

Agency

National Geospatial-Intelligence Agency

- U.S. Department of Energy
- U.S. Department of Health and Human Services
  - Administration for Children and Families
  - Administration for Community Living
  - Centers for Disease Control and Prevention Centers for
  - Medicare & Medicaid Services
  - Food and Drug Administration
  - National Institutes of Health
  - Health Resources and Services Administration

- Substance Abuse and Mental Health Services Administration
- U.S. Department of Homeland Security
- U.S. Department of Housing and Urban Development
- U.S. Department of Justice Drug Enforcement Administration Federal Bureau of Investigation Office of Justice Programs
- U.S. Department of Labor
- U.S. Department of State
- U.S. Department of Transportation Federal Highway Administration
- U.S. Department of the Treasury
- U.S. Department of Veterans Affairs
- U.S. General Services Administration
- Federal Deposit Insurance Corporation
- U.S. Nuclear Regulatory Commission



### CERTIFICATIONS

- Women-owned (WOSB)
- Economically Disadvantaged Women-Owned (EDWOSB)
- 8(a)
- Certified Business Enterprise/Minority Business Enterprise/Small Business Enterprise/Women Business Enterprise (CBE/MBE/SBE/WBE)
- Veteran-owned (VOSB)
- Service-disabled Veteran-owned (SDVOSB)
- Historically Underutilized Business Zones (HUBZone)



### **GovCon LEADERSHIP TEAM**



MICHELLE TAYLOR GovCon Committee, Co-Chair

President and CEO



Email: <u>mtaylor@betah.com</u> <u>https://www.betah.com</u>



JACKIE LOPEZ GovCon Committee, Co-Chair

President



Email: jklopez@pesolutions-it.com

https://www.pesolutions-it.com



THERESA HARRISON BOW Executive Leadership Team

Sr. Managing Partner



Email: theresa@georgestreetinc.com

https://www.georgestreetinc.com/



## BOW MEMBERS DELIVERING EXCELLENCE





Email:

#### Jenna.Reese@Connect-Centric.com

#### Phone:

(703) 650-5680

#### Website:

https://connectcentric.com

## JĒNNA REESE

### CEO CONNECT CENTRIC

YEARS IN BUSINESS: 15 Years

### **GOVERNMENT CUSTOMERS:**

- U.S. Food and Drug Administration
- U.S. Department of Defense
- U.S. Department of the Treasury
- U.S. Department of Interior
- U.S. Environmental Protection Agency
- U.S. General Services Administration

#### **CORE CAPABILITIES:**

- Enterprise IT Application Development and Automation
- Process Maturity (DevSecOps, Data Governance, Workflow Optimization, Analytics)
- Contact Center Technology
- IT Product Delivery
- Operations and Maintenance
- Technology Enablement

#### **CERTIFICATIONS & AWARDS:**

- Women-Owned Small Business
- · Economically Disadvantaged Women-Owned
- SBA Emerging Leader 2019
- 2022 Goldman Sachs 10ksb







Email:

#### amuhammad@embarqsolutions.com

#### Phone:

(410) 303-1113

Website:

https://www.embarqsolutions.com

## AALIYAH MUHAMMAD

### CEO EMBARQ SOLUTIONS

YEARS IN BUSINESS: 12 Years

#### **GOVERNMENT CUSTOMERS:**

- U.S. Food and Drug Administration
- U.S. General Services Administration
- National Oceanic and Atmospheric Administration
- U.S. Department of Defense
   Naval Facilities Engineering Systems Command
   U.S. Department of the Army
  - U.S. Department of the Army
  - U.S. Department of the Army Corps of Engineers
  - U.S. Department of the Air Force

#### CORE CAPABILITIES:

- Facilities Maintenance
- Janitorial

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- Grounds Maintenance
- Project Management







Email:

sjowens@ji-solutions.com

Phone:

(240) 417-1764

Website:

## **SYLVIA L. JOHNSON**

### PRESIDENT/CEO JI-SOLUTIONS LLC

YEARS IN BUSINESS: 14 Years

### **GOVERNMENT CUSTOMERS:**

- U.S. Department of Transportation
- U.S. Department of the Treasury
- State and Local Government

### CORE CAPABILITIES:

- Acquisition & Talent Management
- Health IT & Biomedical Consulting Services

### **CERTIFICATIONS & AWARDS:**

- SBA 8(a) Certified
- Women-Owned Small Business
- Economically Disadvantaged Women-Owned Small Business
- Disadvantaged Business Enterprise
- Small Disadvantaged Business
- Minority Business Enterprise, MDOT
- Minority Business Enterprise, Prince George's County
- North Carolina HUB Certified
- North Carolina Small Business Enterprise

JI - SOLUTIONS Business Made Simple

#### https://ji-solutions.com





#### Email:

Ifranklin@pmcsllc.com or contactus@pmcsllc.com

Phone:

(202) 904-2323

Website:

#### https://www.pmcsllc.com

## LASHELLE FRANKLIN

### CO-OWNER/GENERAL COUNSEL PROFESSIONAL MANAGEMENT CONSULTING SERVICES, LLC.

YEARS IN BUSINESS: 18 Years

#### **GOVERNMENT CUSTOMERS:**

- Internal Revenue Service
- Office of Personnel Management
- Nuclear Regulatory Commission
- National Science Foundation
- U.S. Department of the Army
- U.S. Department of Health and Human Services
- DC Department of General Services

#### **CORE CAPABILITIES:**

- Management
- Organizational Transformation
- Information Technology
- Staffing

#### **CERTIFICATIONS & AWARDS:**

- 8(a) certified
- Small Disadvantaged Business
- ISO/IEC 20000:2018 IT Service Management
  - 8(a) STARS III
- GSA MAS
- OASIS





### **OUR PANELISTS**



### AALIYAH MUHAMMAD





SYLVIA L. JOHNSON President/CEO

JI - SOLUTIONS Business Made Simple

Email: <u>sjowens@ji-solutions.com</u>

https://ji-solutions.com



LASHELLE FRANKLIN

Co-Owner/General Counsel



Email: <u>lfranklin@pmcsllc.com</u> or <u>contactus@pmcsllc.com</u> https://www.pmcsllc.com



For more information, contact us at namers@thebowcollective.org or membership@thebowcollective.org (214) 807-0413



## **Closing Remarks**

Kaitlyn Lowe Branch Chief, Innovations, Systems, and Data Quality



## LUNCH

12 PM – 1 PM

Please order from the Great Room Kiosk in the lobby



## **2024** Women-Owned Small Business Fair

Hosted by the U.S. Food and Drug Administration

