Welcome to the 2021 FDA Virtual Small Business Fair

April 6, 2021

Master of Ceremonies: Chris McMillin

OFBAP| Office of Finance, Budget, Acquisitions, and Planning

Welcome

Leonard Grant, Director of the Office of Acquisition
& Grants Services, FDA

❑ **The Food and Drug Administration (FDA) recognizes that Small Businesses are the backbone of the US Economy**

   o America's 30 million small business owners are the engine of job creation and economic growth in this country

   o Understand the need for greater support (education, information, access) for Small Businesses

❑ **FDA takes the role of partnering with the Small Business Community seriously**

   o FDA historically meets or exceeds its annual Small Business Goals (challenge is HUBZones)

   o Over the years we've hosted two annual Small Business Fairs; one general and one targeting either HUBZones or SDVOSBs

   o As a result of the current health crisis hosted only one in FY20 (virtually)

   o Starting to collect and plan for FY22 requirements (COVID-19 Supplemental Funding-American Rescue Plan)

   o Looking to host next session in Nov 2021 (FY22)

❑ **OAGS staff works closely with the SBA, HHS Office of Small and Disadvantaged Business Utilization (OSDBU), and our Small Business Specialist (Natasha Boyce) to support access to federal contracting opportunities within the FDA**

   o **HHS OSDBU Small Business Customer Experience (SBCX) -** https://mysbcx.hhs.gov

❑ **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, and the CTO)**

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Opening Remarks

Vid Desai, Chief Technology Officer, FDA

FDA IT Demographics

Total Budget FY21 $785M
- Business IT (BIT) $323M
- Enterprise IT (EIT) $462M

Total IT Employees 4034
- Total # EIT Employees: 506 (12.5%)
- Total # BIT Employees: 253 (6.3%)
- Total # of EIT Contractors: 1,346 (33.4%)
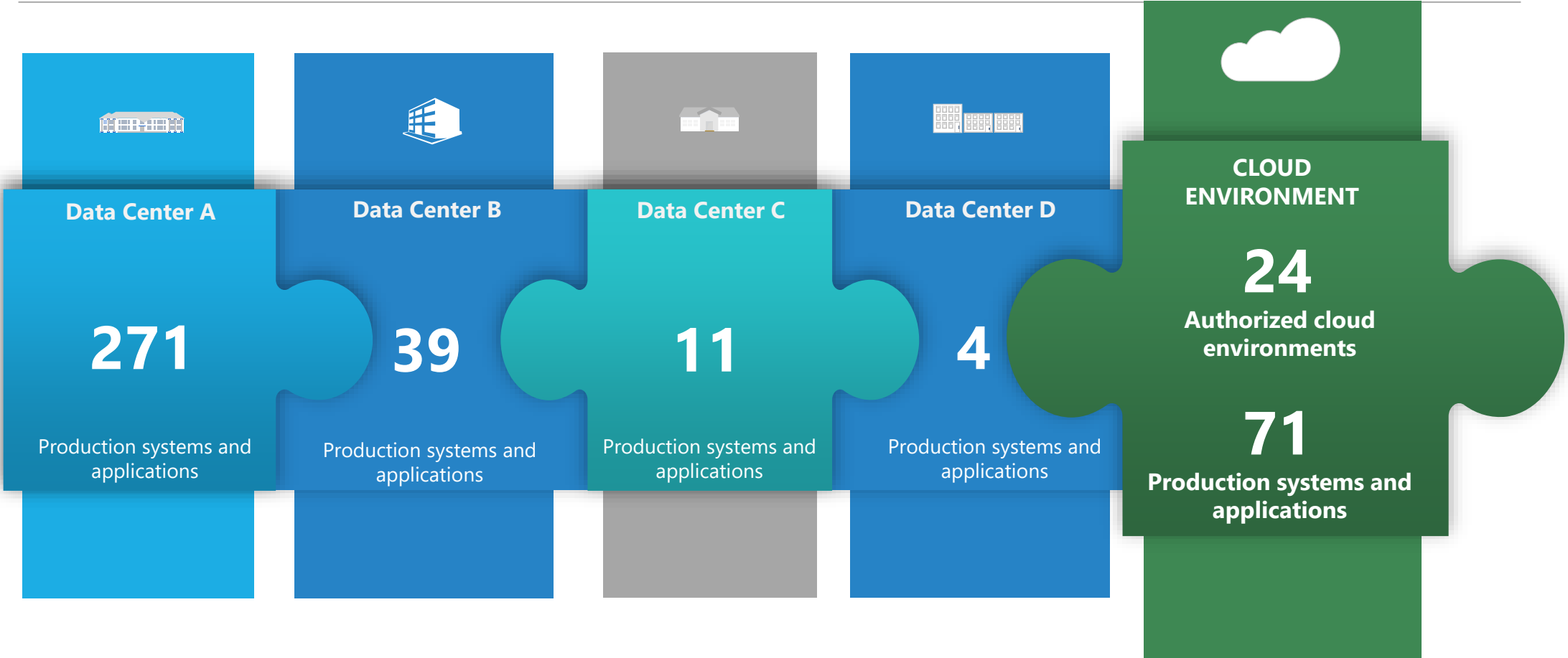- Total # BIT Contractors: 1,929 (47.8%)

Total OIMT Contract Spend (FY20) $248M

Total Systems   396

FDA Computing Environment

Data Center A

271

Production systems and applications

Data Center B

39

Production systems and applications

Data Center C

11

Production systems and applications

Data Center D

4

Production systems and applications

CLOUD ENVIRONMENT

24

Authorized cloud environments
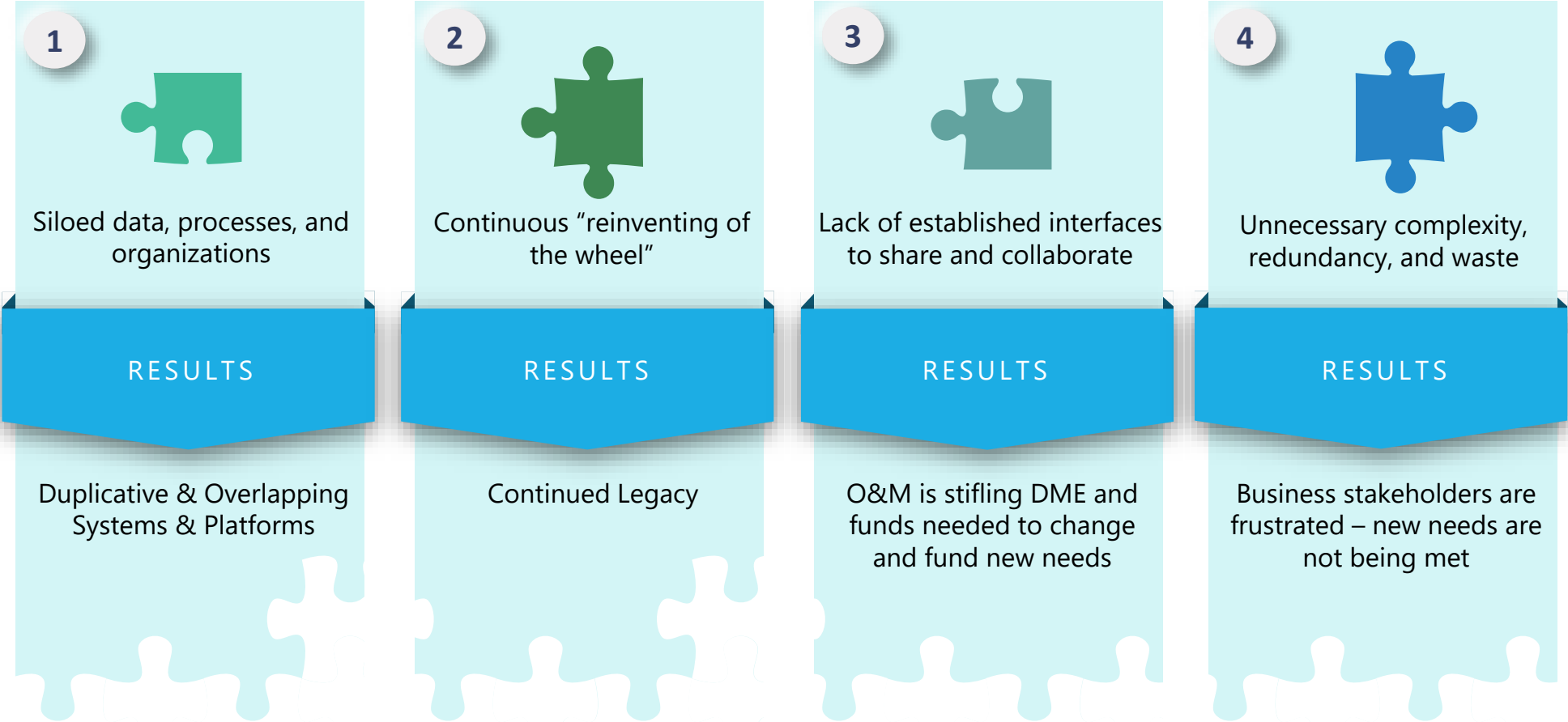
71

Production systems and applications

Good IT is a Team *Sport*

- IT Solutions are interdependent- Center IT and OIMT cannot provide end-to-end IT services efficiently on its own

- Center IT and OIMT have to function well for the FDA to benefit

- The lack of good and planned coordination results in a lot of clumsiness and efficiencies.

We Need **NWOW**

Traditional IT approaches

- Starting with a solution (I need product xyz)…

- "Government is different"

  Our needs require a custom approach…

- Let's start with what we know (As-is systems, tech) and then see how we can "integrate" and get closer to what we need…

- IT Leads business change programs

NWOW

- What is the problem we're trying to solve?
- What data/information can provide the best answer?
- How can we best get that data/information quickly, accurately and consistently when needed?
- IT Supports Business Change Programs

What does great IT look like?

Matured, Modernized IT Operations

Well defined Service levels delivering quality operations.

Focus on Service optimization

Financial Management

Business priorities aligned with IT Spend aligned in supporting business outcomes

Planning and Alignment

Strategic & Operating Plans coordinated across EIT and BIT. Data treated as a visible, strategic asset
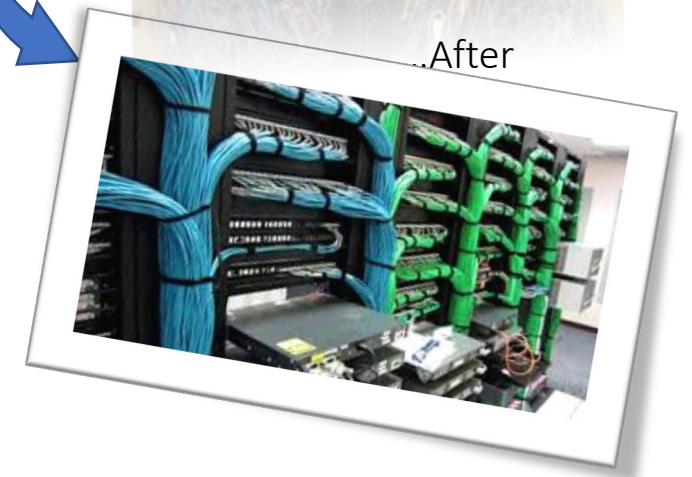
Governance

Well-organized IT and data governance empowering strategic and tactical decisions

Before…

…After

So how do we *fix* this?

Agree on a tried & tested Industry Standard framework and processes for all IT activity

Framework needs to be comprehensive and cover everything that is needed to operate IT and remain modern

Align with this one Industry standard framework

Before addressing who & what we need, we need to agree what is important and how should that be done?

The answer is **ITIL**

General management practices

Architecture management	Continual improvement	**Information security management**
Knowledge management	Measurement and reporting	Organizational change management
Portfolio management	**Project management**	Relationship management
Risk management	**Service financial management**	**Strategy management**
Supplier management	Workforce and talent management	

Service management practices

Availability management	Business analysis	Capacity and performance management	**Change Control**
Incident management	IT asset management	**Monitoring and event management**	**Problem management**
Release management	Service catalog management	Service configuration management	Service continuity management
Service design	Service desk	Service level management	Service request management
Service validation and testing			

Technical management practices

Deployment management	Infrastructure and platform management	**Software development and mgmt.**

Key Governance principles

Adopt standard industry frameworks

- Align with TBM model for financial transparency

- ITIL for IT Processes

Align Strategy to drive the same IT metrics

- IT cost per Employee

- Consider Employee to Contractor ratio
  - Recommend 60:40 or better

- Consider O&M vs. DME spend
  - Recommend 80% O&M or less and 20% or greater for DME

Incentivize sharing and re-use

- Invest in solving new problems instead of "perfecting existing solutions"

- Good enough is good enough…

Benefit from economies of scale (O&M to DME)

- Common license management, procurement, contracts and vendor management (also covered by ITIL processes)

Don't outsource Planning, Thinking & Decision making…

Questions/Discussion

CONTACT: VID.DESAI@FDA.HHS.GOV

FDA Office of Acquisitions and Grants Services (OAGS) Overview

Bryan Jones

Director, Division of Policy Systems and Program Support

What FDA's Mission Means for OAGS

What FDA's Mission Means for OAGS

- 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.

How We are Organized
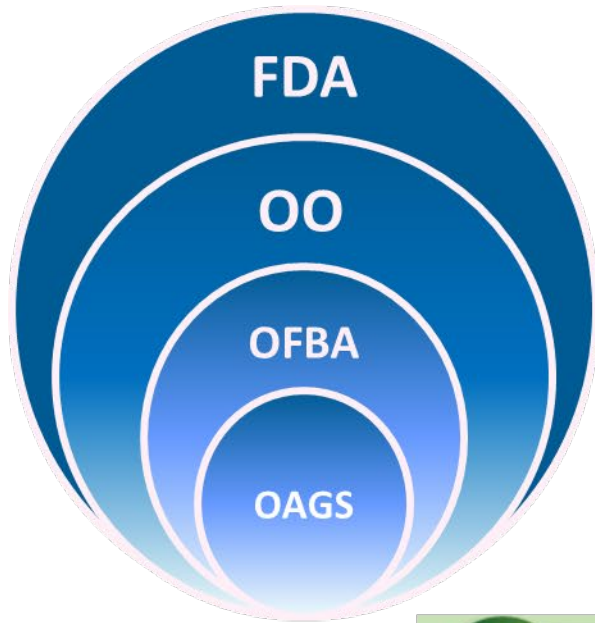
- **Office of Operations**—provides mission support services across FDA, including budgeting, personnel, property, IT, employee safety, security, program effectiveness

- **Office of Finance, Budget, and Acquisitions**— leads financial management, budget, and acquisitions functions, under Jay Tyler, CFO

- **Office of Acquisitions and Grants Services (OAGS)**

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OFFICE OF ACQUISITIONS AND GRANTS SERVICES

Office Director
Leonard Grant

Senior Acquisition Advisor
Ted Weitzman

Associate Director
Ron Loube

Associate Director
Vacant

▮	Division
▮	Branch
▮	Team

Training and Development Branch
James O'Keefe

P-card Team

Grant Monitoring Team

Division of Grants, Agreements and Acquisition Support (DGAAS)
Vacant

Division of Acquisition Operations (DAO)
Vidya Vish

Division of Acquisition Programs (DAP)
Sandy Bellinger

Division of Information Technology Acquisitions (DITA)
Andrew Jernell

Division of Policy, Systems, and Program Support (DPSPS)
Bryan Jones

Grants and Assistance Agreements Branch
Kim Pendleton

Service Contracts Branch
James Whitt

Field Operations Branch
Regina Williams

IT Acquisitions Branch
Sherry Solodkova

Acquisition Policy Branch
Josephine Chutta

Contract Admin Branch
Vacant

Also Consisting of:
IAA (4 people),
Invoices (3 people),
Closeout (2 people)

Contract Operations Branch
Gary Klaff

Facilities Support Branch
Monifa Coleman

System Technology Acquisitions Branch
Steven Chang

Innovation Systems & Data Quality Branch
Vacant

Scientific Support Branch
Terry Frederick (Acting)

ORA Inspection Contracts Branch
Cynthia Martin (Acting)

IT Strategic Support Branch
Phillip Frame

CTP Inspection Contracts Branch
Erika Eam

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How We are Organized

FDA

Innovation, Systems & Data Quality Branch
Provides system support and serves as the PRISM, UFMS, FPDS, WorkSmarter and AAP focal point for OAGS. Tracks and analyze acquisition data, performs audits of acquisition actions, and supports program acquisition needs, i.e. IGCEs, SOWs, Evaluation Criteria, etc. Looks for innovative ways to promote office efficiency and effectiveness

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

Grants and Assistance Agreements Branch
Negotiate, award and monitor federal funds awarded through various grant mechanisms. Award and administer Inter-Agency Agreements (IAGs)

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.

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

Contract Operations Branch
Service contracts and simplified acquisitions, including but not limited to, studies, chemicals/ drugs/reagents, animals, lab equipment, etc.

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

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)

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

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

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, FAC-COR, FAC-P/PM

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Centers/Offices that OAGS Supports

Center for Biologics Evaluation and Research (CBER)

Center for Drug Evaluation and Research (CDER)

Center for Devices and Radiological Health (CDRH)

Center for Food Safety and Applied Nutrition (CFSAN)

Center for Tobacco Products (CTP)

Center for Veterinary Medicine (CVM)

National Center for Toxicological Research (NCTR)

Office of Information Management and Technology (OIMT)

Office of Regulatory Affairs (ORA)

Office of the Commissioner/Office of Operations (OC/OO)

For more information on each Center/Office and its mission please visit www.fda.gov.

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Commodities and Services Purchased

FDA

- ❑ **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.)**

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

FDA's FY2020 Statistics

Fiscal Year 2020
Statistics for OAGS

FDA

Purchase Card Data	FY 18	FY 19	FY 20
Transaction	$66.2 M	$70.6 M	$67.5 M
# of Transactions	92,225	87,172	77,421
Cardholder Accounts (Average)	815	804	812
Convenience Check Spend	$153,822	$118,584	$79,045
Convenience Check Transaction #	146	124	78
Rebates Earned	$0.94 M	$1.05 M	$1.23 M

Grant Data	FY 18	FY 19	FY20
New Competing Grants	165	145	239
Non-competing Continuation Grants	389	405	321
Total Obligated	$199.2 M	$225 M	$224 M

Fiscal Year Totals*	FY 18	FY 19	FY 20
Actions Awarded	6,074	6,115	6,560
Total Obligated	$2.00 B	$2.11 B	$2.22 B

*Doesn't include P-Card Data which is obligated external to OAGS nor IAA Reimbursable Dollars which are not considered obligations.

Interagency Agreement Data	FY 18	FY 19	FY 20
Reimbursable IAAs	55	61	67
Reimbursable IAA Dollar Value (Funds-in)	$33 M	$32 M	$42 M
Service IAAs (Funds-out)	601	478	621
Service IAAs Total Value	$402.7 M	$288.8 M	$ 258.8 M
Total Awarded	656	539	688
Total Obligated	$402.5 M	$320.8 M	$300.1 M

Contracts (Including PO) Data (DCIS)	FY 18	FY 19	FY 20
Awarded Contracts	4,864	5,087	5,379
Total Obligated	$1.4 B	$1.6 B	$1.7 B

FY20 Statistics for OAGS

NUMBER OF ACTIONS BY CENTER FY20

- CBER, 551, 10%
- CDER, 1064, 20%
- CDRH, 272, 5%
- CFSAN, 481, 9%
- CTP, 452, 8%
- CVM, 162, 3%
- NCTR, 323, 6%
- OC, 783, 15%
- OIMT, 389, 7%
- ORA, 902, 17%
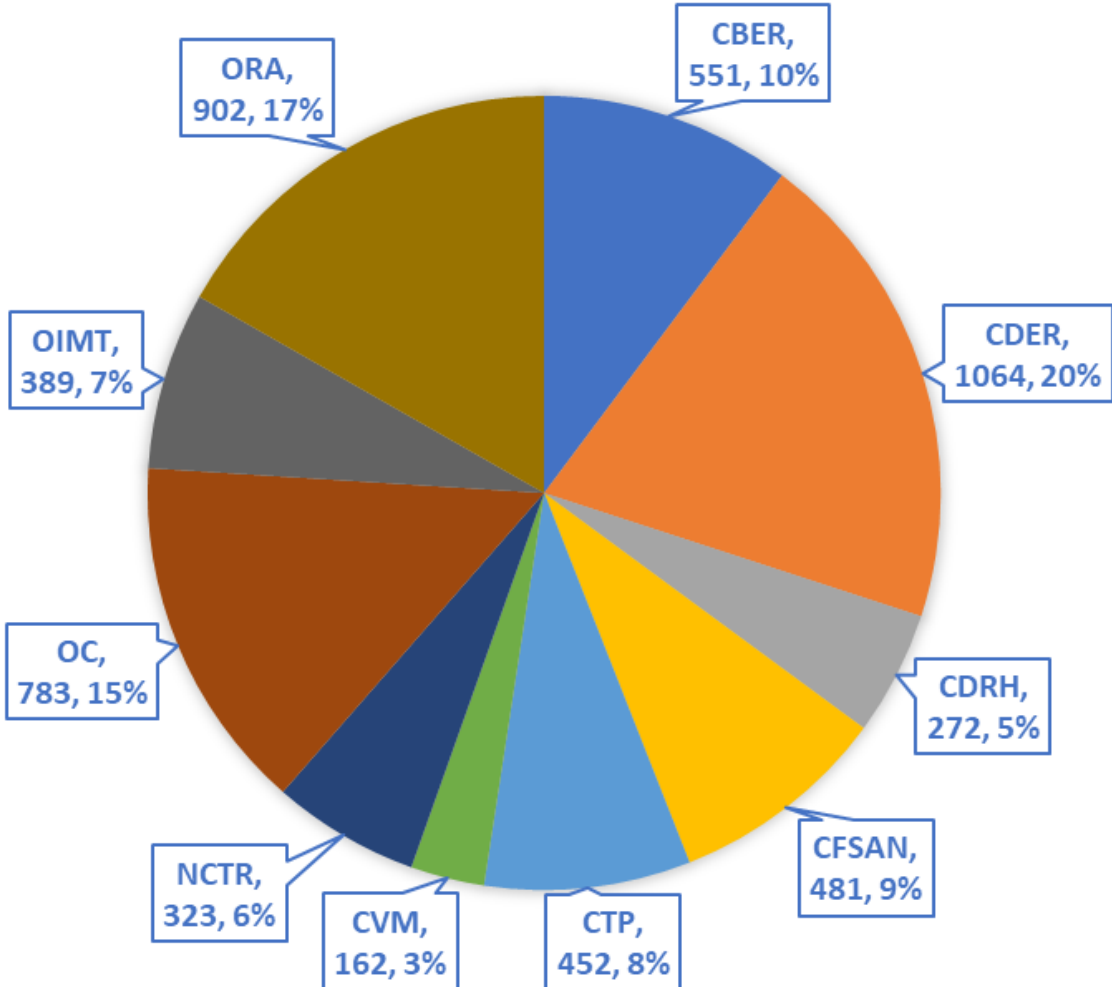
Note: This data only represents Contract Awards, not IAAs or Grants

FY20 Statistics for OAGS

AMOUNT OBLIGATED BY CENTER FY20

ORA, $116,669,562.62, 6%
CBER, $121,350,230.68, 7%
OIMT, $317,920,304.05, 18%
CDER, $408,201,537.04, 23%
CDRH, $87,118,907.36, 5%
CFSAN, $66,021,160.33, 4%
CTP, $326,872,111.07, 18%
CVM, $13,071,705.95, 1%
NCTR, $25,675,337.35, 1%
OC, $315,742,048.82, 17%
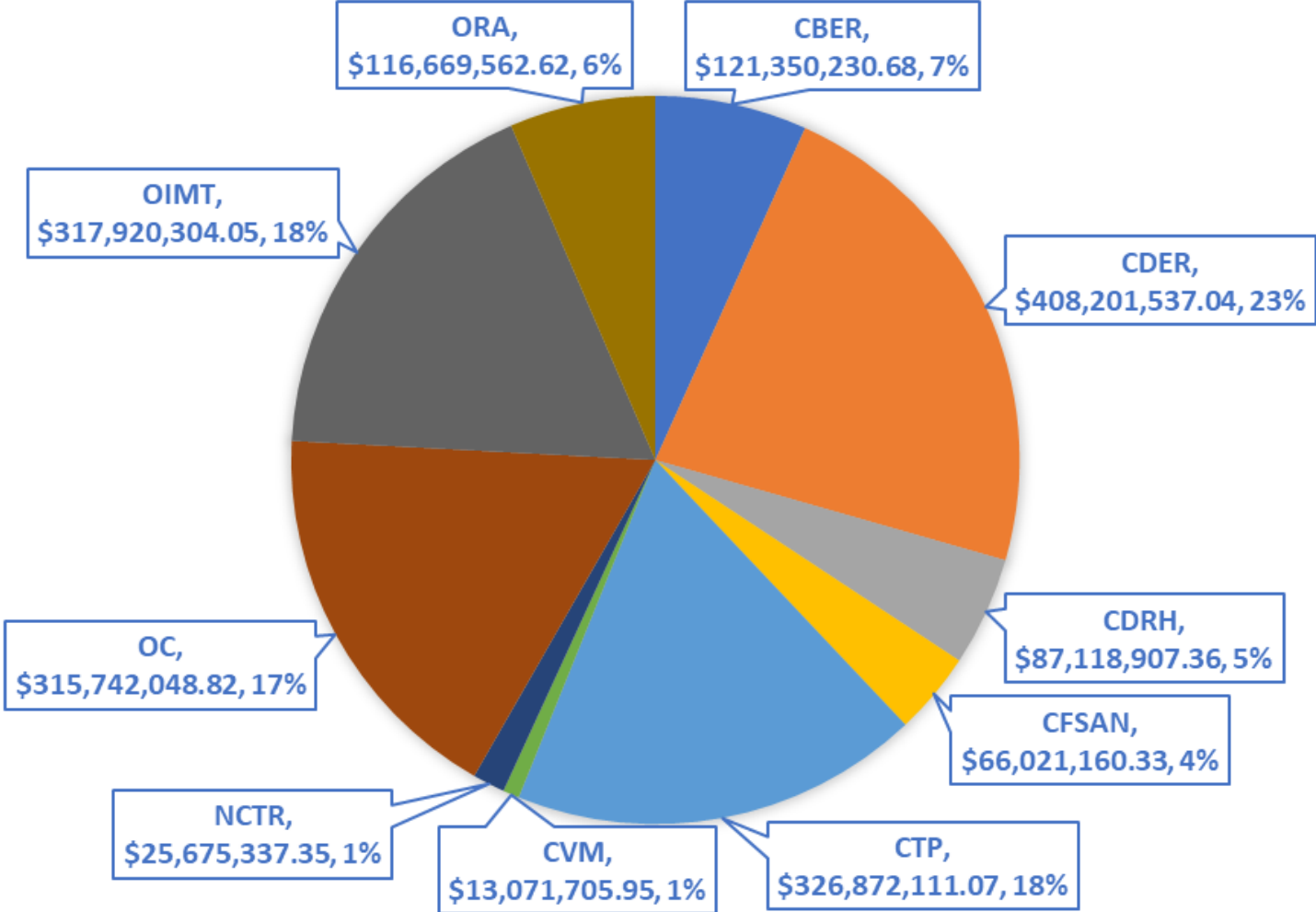
Note: This data only represents Contract Awards, not IAAs or Grants

FY 20 - TOP 20 NAICS BY ACTIONS

Rank	NAICS Code	Description	Contract Actions	% of Total Actions
1	334516	ANALYTICAL LABORATORY INSTRUMENT MANUFACTURING	517	18.9%
2	541519	OTHER COMPUTER RELATED SERVICES	445	16.2%
3	541611	ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES	349	12.7%
4	811219	OTHER ELECTRONIC AND PRECISION EQUIPMENT REPAIR AND MAINTENANCE	194	7.1%
5	541990	ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	191	7.0%
6	923120	ADMINISTRATION OF PUBLIC HEALTH PROGRAMS	179	6.5%
7	541512	COMPUTER SYSTEMS DESIGN SERVICES	140	5.1%
8	541511	CUSTOM COMPUTER PROGRAMMING SERVICES	124	4.5%
9	561210	FACILITIES SUPPORT SERVICES	111	4.0%
10	541690	OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES	80	2.9%
11	511210	SOFTWARE PUBLISHERS	68	2.5%
12	518210	DATA PROCESSING, HOSTING, AND RELATED SERVICES	51	1.9%
13	611430	PROFESSIONAL AND MANAGEMENT DEVELOPMENT TRAINING	46	1.7%
14	511120	PERIODICAL PUBLISHERS	45	1.6%
15	541714	RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY (EXCEPT NANOBIOTECHNOLOGY)	39	1.4%
16	334111	ELECTRONIC COMPUTER MANUFACTURING	37	1.3%
17	325414	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING	34	1.2%
18	561320	TEMPORARY HELP SERVICES	33	1.2%
19	339113	SURGICAL APPLIANCE AND SUPPLIES MANUFACTURING	31	1.1%
20	519130	INTERNET PUBLISHING AND BROADCASTING AND WEB SEARCH PORTALS	27	1.0%
	Grand Total		**2741**	**100%**

FY 20 - TOP 20 NAICS BY DOLLARS

FDA

Rank	NAICS Code	Description	Dollars Obligated	Average	% of Dollars Obligated
1	541519	OTHER COMPUTER RELATED SERVICES	$ 294,604,697.70	$ 662,033.03	18.4%
2	541611	ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES	$ 265,181,297.60	$ 759,831.80	16.6%
3	541512	COMPUTER SYSTEMS DESIGN SERVICES	$ 262,718,564.27	$ 1,876,561.17	16.4%
4	541810	ADVERTISING AGENCIES	$ 163,877,180.42	$27,312,863.40	10.2%
5	541511	CUSTOM COMPUTER PROGRAMMING SERVICES	$ 138,167,783.66	$ 1,114,256.32	8.6%
6	541990	ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	$ 123,579,006.17	$ 647,010.50	7.7%
7	518210	DATA PROCESSING, HOSTING, AND RELATED SERVICES	$ 78,423,369.64	$ 1,537,713.13	4.9%
8	923120	ADMINISTRATION OF PUBLIC HEALTH PROGRAMS	$ 47,974,199.53	$ 268,012.29	3.0%
9	334516	ANALYTICAL LABORATORY INSTRUMENT MANUFACTURING	$ 45,249,734.18	$ 87,523.66	2.8%
10	334111	ELECTRONIC COMPUTER MANUFACTURING	$ 26,483,858.47	$ 715,779.96	1.7%
11	541714	RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY (EXCEPT NANOBIOTECHNOLOGY)	$ 23,616,644.81	$ 605,555.00	1.5%
12	541690	OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES	$ 22,506,860.06	$ 281,335.75	1.4%
13	561210	FACILITIES SUPPORT SERVICES	$ 21,140,722.49	$ 190,456.96	1.3%
14	541910	MARKETING RESEARCH AND PUBLIC OPINION POLLING	$ 13,620,593.46	$ 851,287.09	0.9%
15	541711	RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY	$ 12,918,674.94	$ 922,762.50	0.8%
16	511210	SOFTWARE PUBLISHERS	$ 12,242,035.14	$ 180,029.93	0.8%
17	221122	ELECTRIC POWER DISTRIBUTION	$ 12,210,638.55	$ 4,070,212.85	0.8%
18	325412	PHARMACEUTICAL PREPARATION MANUFACTURING	$ 11,918,578.00	$ 1,324,286.44	0.7%
19	811219	OTHER ELECTRONIC AND PRECISION EQUIPMENT REPAIR AND MAINTENANCE	$ 11,875,511.89	$ 61,213.98	0.7%
20	541715	RESEARCH AND DEVELOPMENT IN THE PHYSICAL, ENGINEERING, AND LIFE SCIENCES (EXCEPT NANOTECHNOLOGY AND BIOTECHNOLOGY)	$ 11,220,495.07	$ 431,557.50	0.7%
		Grand Total	**$1,599,530,446**	**$511,181**	**100%**

FDA's Goals

FDA SOCIOECONOMIC GOALS

Small Business Award Categories	FY Goal*	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20
Small Businesses	38% (35% until FY14) (43% in FY 14)	48.93%	43.28%	50.10%	48.5%	39.64%	36.8%	39.06%	40.09%
Small Disadvantaged Businesses	5.0%	30.69%	25.28%	29.50%	27.9%	24.31%	25.0%	27.14%	26.96%
Women-Owned Small Businesses	5.0%	9.92%	13.63%	15.90%	17.8%	14.22%	14.1%	14.13%	12.68%
HubZone Businesses	3.0%	2.59%	3.61%	2.20%	2.0%	1.40%	1.8%	2.75%	4.09%
Service Disabled Veteran Owned	3.0%	2.14%	2.93%	3.17%	4.9%	3.42%	3.4%	2.81%	3.91%

In 2020, FDA awarded more than $693 Million to Small Businesses!!!

FDA Competition Data

Center	Percent of Eligible Actions Competed	Percent of Eligible Dollars Competed
HHS Goal	**65%**	**75%**
FY16	91%	94%
FY17	90%	96%
FY18	89%	96%
FY19	90%	94%
FY20	**91%**	**96%**

DITA:
Division of Information Technology Acquisitions Opportunities

DITA: FY21 Opportunities Below SAT

Detailed Description	Opportunity Type	Anticipated RFP/RFQ Release	Center
Portworx License Renewal	Less than $250K		
	Less than $250K		
	Less than $250K		
	Less than $250K		
	Less than $250K		

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DITA: FY21 Opportunity Above the SAT

Oracle Database Administration Support (DBA) IDIQ: The FDA requires ongoing operations and maintenance support on Oracle database and application servers hosting FDA centers applications (hardware and software)

Current Award Detail:

- ✓ Current/Previous Contract Number: HHSF223201610017I
- ✓ Current Contract Expiration Date: 8/21/2021

Details:

NAICS	541519
Anticipated Solicitation Date	July 2021
Estimated Project Value	*57M*
Set-aside	8a Competitive
Center/Office Point of Contact(s)	Delores Johnson
OAGS Point of Contact	Jackie Ngegba

DITA: FY21 Opportunity Above the SAT

Enterprise Business Objects IDIQ: The purpose of this IDIQ is to provide a contract vehicle to the FDA to provide full system life cycle support services for the existing EBO SAP Business Intelligence (BI) software application and all its environments.

Current Award Detail:

- ✓ Current/Previous Contract Number: HHSF223201610004B
- ✓ Current Contract Expiration Date: 3/16/2020

Details:

NAICS	541519
Anticipated Solicitation Date	July 2020
Estimated Project Value	*17M*
Set-aside	either directed alaskan/tribal 8a or competitive SB GSA BPA
Center/Office Point of Contact(s)	Angela Williams
OAGS Point of Contact	Jackie Ngegba

DITA: FY21 Opportunity Above the SAT

FDA Helpdesk : The purpose of this BPA is to obtain IT support services providing the full range of technical support, project management, and call center management services necessary to manage and maintain a multi-tier IT helpdesk call center; support for account management and peripheral devices; and support for the assessment and validation of new or updated technologies.

Current Award Detail:

✓ Current/Previous Contract Number: HHSF223201510016B

✓ Current Contract Expiration Date: Active order expires 08/31/2021

Details:

NAICS	541519
Anticipated Solicitation Date	April 2021
Estimated Project Value	Above $20M
Set-aside	Small Business, not sure if a subset
Center/Office Point of Contact(s)	OIMT
OAGS Point of Contact	Peter Lee, Peter.Lee@fda.hhs.gov

Potential Subcontracting Opportunities

FDA

OAGS DIVISION	Purchase Request Title	Detailed Description	Opportunity Type	Anticipated RFP/RFQ Release	Center
DITA/ITAB	Oracle Database Adminstration Support (DBA)	The FDA requires ongoing operations and maintenance support on Oracle database and application servers hosting FDA centers applications (hardware and software)	Subcontracting Possibility	7/1/2021	OIMT
DITA/ITAB	Enterprise Business Objects	The purpose of this IDIQ is to provide a contract vehicle to the FDA to provide full system life cycle support services for the existing EBO SAP Business Intelligence (BI) software application and all its environments.	Subcontracting Possibility	7/1/2021	OIMT

DAO: FY21 Opportunities Below SAT

Detailed Description	Opportunity Type	Anticipated RFP/RFQ Release	Center
Conduct market research in select targeted areas in support of FDA Foods Standards Program	Less than $250K	7/1/2021	CFSAN

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DAO: FY21 Opportunity Above the SAT

[FDA Nationwide Security Maintenance and Installation]: The scope of this IDIQ contract includes providing the hardware and complete range of technical support services necessary to secure all FDA facilities nationwide for the protection of people and property.

Current Award Detail:

- ✓ Current/Previous Contract Number: HHSF201710016I
- ✓ Current Contract Expiration Date: 12/19/2020

Details:

NAICS	561621
Anticipated Solicitation Date	April 30, 2021
Estimated Project Value	Above $20 million
Set-aside	Competitive 8(a)
Center/Office Point of Contact(s)	Tampathi Carroll-McIntyre
OAGS Point of Contact	James Whitt

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DAP:
Division of
Acquisition
Programs
Opportunities

DAP: FY21 Opportunities Below SAT

FDA

Detailed Description	Opportunity Type	Anticipated RFP/RFQ Release	Center
Programmable Logic Controller & UV System Upgrade	Less than $250,000	3rd Quarter	ORA
Services to measure concentration of proteins	Less than $250,000	3rd Quarter	NCTR
DCDA (Division of Complex Drug Analysis) needs to purchase an Advanced Electrospray Aerosol Generator system, 1-year warranty, and installation and training at DCDA.	Less than $250,000	3rd Quarter	CDER
CONVIRON Model GEN2000 Chambers purchase for the Produce Safety Consortium Projects	Less than $250,000	3rd Quarter	CFSAN
UHPLC with Diode Array Detector	Less than $250,000	3rd Quarter	CDER
DM 49-2 Preventative Maintenance Agreement (PMA) for BioSMB PMA, Base and four options	Less than $250,000	3rd Quarter	CDER

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DAP: FY21 Opportunity Above the SAT

FDA

Operations and Maintenance of Facility Services at Jefferson Lab Complex: Purpose of the project is to procure a contractor for on-site facility operations and maintenance support services to perform a full range of operational and maintenance support including Work Order (WO)/Indefinite Delivery Indefinite Quantity (IDIQ) work services to the National Center for Toxicological Research.

Current Award Detail:

✓ Current/Previous Contract Number: HHSF223201610036I

✓ Current Contract Expiration Date: 9/2021

Details:

NAICS	561210
Anticipated Solicitation Date	Quarter 3, FY 21
Estimated Project Value	*Above $20M*
Set-aside	Small Business
Center/Office Point of Contact(s)	Glen Strain
OAGS Point of Contact	Warren Dutter

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DAP: FY21 Opportunity Above the SAT

Management Consulting and Professional Services BPA: 1)Advisory/Subject Matter Expert Services; 2) Business Process Improvement; 3) Change Management Strategy; 4) Communications Strategy Support; 5) Evaluation Strategy Develop; 6) Program/Project Management; 7) Quantitative/Qualitative Modeling, Analysis & Reporting Leverage a wide range of quantitative and qualitative analytical methods to support; 8) Resource Capacity Planning; 9) Risk Management Strategy Support; 9) Risk Management Strategy Support; 10) Strategic Planning

Current Award Detail:

✓ Current/Previous Contract Number: N/A

✓ Current Contract Expiration Date: N/A

Details:

NAICS	541611
Anticipated Solicitation Date	3rd Quarter, FY 21
Estimated Project Value	Above $20M
Set-aside	BPA with Small Business Reserves
Center/Office Point of Contact(s)	Maria Sagoua
OAGS Point of Contact	Yvette Brown

DAP: FY21 Opportunity Above the SAT

FDA Agency Hazardous Waste: Comprehensive waste management services for the collection, transportation and disposal of chemical and radioactive waste generated by the FDA Nationwide, including Puerto Rico.

Current Award Detail:

✓ Current/Previous Contract Number: HHSF223201610026I

✓ Current Contract Expiration Date: 8/31/2021

Details:

NAICS	562211
Anticipated Solicitation Date	3rd Quarter
Estimated Project Value	Less than $5 million
Set-aside	TBD
Center/Office Point of Contact(s)	Timothy Jiggens
OAGS Point of Contact	Emmanuel Mbah

Keys to Conducting Business with the FDA

Conducting Business with the FDA

- Contact Small Business Program Office: www.hhs.gov/about/smallbusiness/

- The FDA Forecast Information can be found on the HHS SBCX website: https://mysbcx.hhs.gov/#home
  - Click to Government, then Forecast Opportunities, and make a SBCX Account

- Obtain a DUNS number from Dun & Bradstreet and Register in System for Award Management (SAM).
  - A DUNS number is a business identification number and businesses must have a DUNS number to do business with the Federal Government. You must be registered in SAM to do business with the Federal government. www.sam.gov

Conducting Business with the FDA

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

- Pursue GWAC vehicles: NASA SEWP, NITAAC, STARS II, Best in Class Vehicles

- Visit SAM.gov at https://beta.sam.gov/ & Search by Contract Opportunities

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

- Explore Subcontracting Opportunities and network with Large Businesses/Primes

Conducting Business with the FDA

- Respond to Requests for Information (RFI) / Sources Sought Notices
  - ➤ Submit sufficient details to support contractor capabilities.

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

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

Thank you!

OFBAP| Office of Finance, Budget, Acquisitions, and Planning

Question and Answer Panel with OAGS Contracting Officers

Panel Introductions

Ted Weitzman, Senior Acquisition Advisor

Andrew Jernell, Division Director, DITA

Vidya Vish, Division Director, DAO

Sandra Bellinger, Division Director, DAP

Question: How does the FDA collect the information for the Forecast of Opportunities? Where is this information posted? How often is this information updated?

Question: How are IT equipment and services procured at the FDA? How has the utilization of Best-in-Class, GWACs, and Category Management impacted DITA?

Question: What approach does your Division use to meet with small businesses and learn about their capabilities? How has the virtual environment affected this approach?

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

Question: Please discuss how your Division is utilizing innovative methods in the contracting process.

Question: What mistakes are common in vendor's proposals that prevent them from being successful offerors?

Question: In your experience as a Contracting Officer, does past performance as an evaluation factor detrimentally affect small businesses?

Question: FDA often utilizes BPA awards through GSA schedules. How can small business learn about these opportunities before RFP release?

Question: Do you maintain a list of vendors that are specifically interested in purchase card and simplified acquisition opportunities to fulfill your short-term procurement requirements?

Thank you!

For Questions and Feedback, please email:
FDA-Small_Business_Outreach@fda.hhs.gov

Center for Food Safety and Nutrition (CFSAN)

Theresa Caesar
Teiana Poullard

April 6, 2021

Mission

CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

What Does CFSAN Do?

- CFSAN is responsible for:
  - Regulations and policy governing food and cosmetic safety
  - Research to address health risks associated with foodborne, chemical, and biological contaminants
  - Postmarket surveillance and compliance
  - Industry outreach and consumer education
  - Cooperative programs with state, local, and tribal governments
  - International food standard and safety harmonization efforts

What Does CFSAN Do? (cont.)

- CFSAN provides services to:
  - Consumers
  - Domestic and foreign industry
  - Other outside groups

- CFSAN executes:
  - Agency administrative tasks
  - Scientific analysis and support
  - Policy, planning and handling of critical issues related to food and cosmetics

Who Works for CFSAN?

Over 1095 employees, including:

• Chemists	•Pharmacologists
• Microbiologists	•Nutritionists
• Toxicologists	•Epidemiologists
• Food Technologists	•Mathematicians
• Pathologists	•Sanitarians
• Molecular Biologists	•Physicians
•Program Specialists	•Veterinarians
	•Budget Analyst

CFSAN Leadership
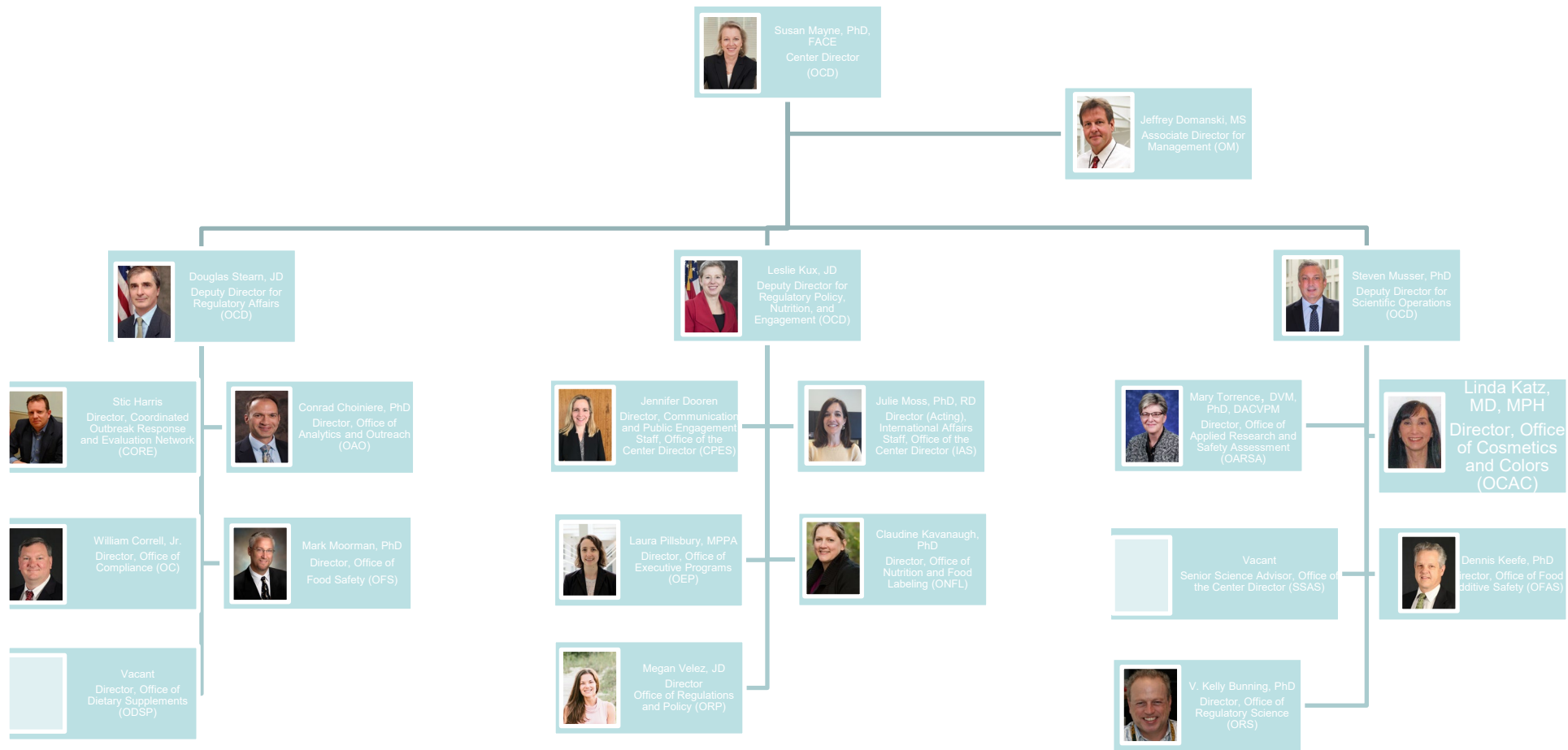
CFSAN Program Offices

- Office of the Center Director (OCD)
- Office of Analytics and Outreach (OAO)
- Office of Applied Research and Safety Assessment (OARSA)
- Office of Compliance (OC)
- Office of Cosmetics and Colors (OCC)
- Office of Dietary Supplement Programs (ODSP)
- Office of Food Safety (OFS)

- Office of Management (OM)
- Office of Nutrition and Food Labeling (ONFL)
- Office of Regulations and Policy (ORP)
- Office of Regulatory Science (ORS)
- Coordinated Outbreak Response and Evaluation Network (CORE)
- Office of Food Additive Safety (OFAS)

CFSAN Core Areas

Food Safety

Nutrition & Food Labeling

Dietary Supplements

Cosmetics & Colors

Current CFSAN Locations

Harvey W. Wiley Federal Building, College Park, MD

CFSAN Headquarters

University Station, College Park, MD

Office of Cosmetics and Colors
Office of Food Additive Safety

Module 1, Muirkirk Road Complex, Laurel, MD

Office of Applied Research and Safety Assessment

Moffett Center, Summit-Argo, Illinois

Office of Food Safety, Division of Food Processing Science and Technology

Gulf Coast Seafood Laboratory, Dauphin Island, AL

Office of Food Safety, Division of Seafood Science and Technology

CFSAN's Strategic Initiatives in FY 21*

- FSMA Implementation & New Era of Smarter Food Safety*
  - Foodborne Illness and Outbreak Response*
    - Nutrition Innovation Strategy
      - Cosmetics Modernization
        - Dietary Supplements
  - Food Product & Ingredient Innovation

Food safety issues are done in coordination with Office of Food Policy & Response

Types of Acquisition Services and Supplies

- Scientific Support Services

- Research and Analysis Service

- Facility Support Services

Types of Acquisition Services and Supplies (cont.)

- Information Technology Services

- Professional Training Services

Types of Acquisition Services and Supplies (cont.)

- Educational Campaigns on Food Safety and Nutrition

- Management Consulting Services

- Administrative Support

Types of Acquisition Services and Supplies (cont.)

- Scientific Equipment and Maintenance

- Office Equipment and Maintenance

- Office Supplies

Trivia

- How many office locations does CFSAN have ?

  A. 3

  B. 5

  C. 2

- What does CFSAN do?

  A. Policy, planning and handling of critical issues   related to food and cosmetics   B. Provides supplies products and communications for   U.S. government offices

  C. Offers vocational services

Contact CFSAN

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Outreach and Information Center
5001 Campus Drive
College Park, MD 20740-3835

Telephone:1-888-SAFEFOOD
(1-888-723-3366)

WEB: http://cfsan.force.com/Inquirypage

Discussion Topics

1. Overview of SEBA

2. Our success story at HHS

3. Successes and Lessons Learned

4. Small business takeaways

Presented by:

Erhiuvie Abu, President and CEO

Erhiuvie Abu is the founder of SEBA Professional Services, and currently serves as its President and Chief Executive Officer.

Ms. Abu has over a decade of experience in project management and financial consulting and is skilled at delivering innovative financial and program management solutions to federal government agencies and commercial clients. She has led engagements with several agencies including the Department of Housing and Urban Development, Department of Treasury, Department of Health and Human Services and the Department of Defense.

Ms. Abu is a Certified Public Accountant (CPA), a Project Management Professional (PMP) and a Certified Six Sigma Black Belt. She earned a Bachelor of Science (BS) degree from George Mason University in Accounting and Management Information Systems and a Masters in Business Administration (MBA) from Johns Hopkins University.

Overview of SEBA

SBA Certified Socio-Economic Statuses:

Contract Vehicles:

GSA Professional Services (PSS) & MAS Schedules
(Prime GSA Contract No.GS-23F-057AA)

OASIS Small Business Pool 1
(Prime GSA Contract No.47QRAD20D1210)

OASIS 8(a) Sub Pool 1
(Prime GSA Contract No.47QRAD20D8164)

Local Government
SEBA is a Maryland Department of Transportation Certified Minority Business Enterprise (MBE).

Company Information

DUNS: 808357045
Cage Code: 51KY2

Locations:
6811 Kenilworth Ave.
Suite 500-E3
Riverdale, MD
20737

1325 G Street, NW
Suite 500
Washington, DC
20005

www.sebapro.com

Click Here for link to NAICS Codes

Core Competences

- Program & Project Management

- Healthcare & Administrative Staffing

- Construction Management

- Financial Advisory

- Training and Development

SEBA's Clients

Key Milestones

SEBA
PROFESSIONAL SERVICES, LLC

2007
- Started business
- Focused mainly on subcontracting
- Focused primarily on financial services

2010
- Obtained 8(a) certification
- Won first Prime Contract in 2011
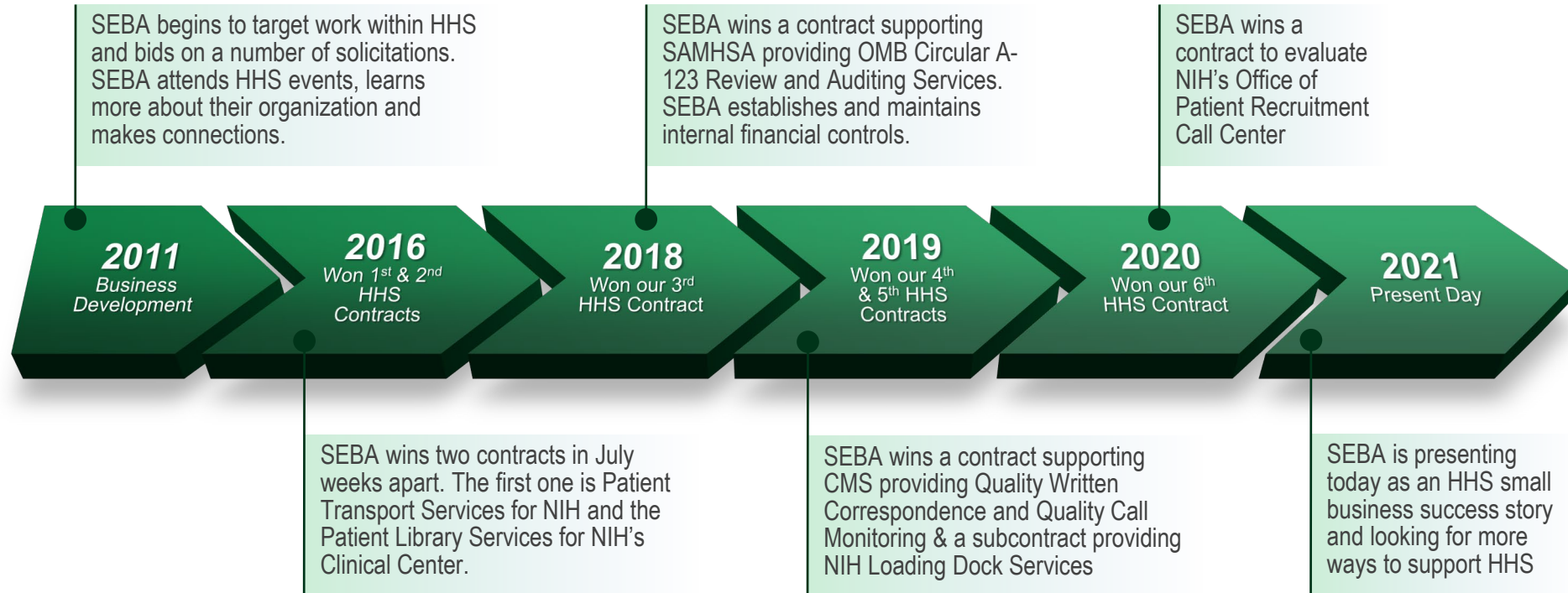- Focused on building relationships with clients and with teaming partners

2019
- Graduated from the 8(a) program
- Focused on utilizing contract vehicles such as GSA MAS schedule and OASIS

2020
- Focus on mentoring other 8(a) firms and small businesses
- Leverage experience to support other firms and grow business
- Continue to build strategic partnerships

SEBA and HHS History

SEBA begins to target work within HHS and bids on a number of solicitations. SEBA attends HHS events, learns more about their organization and makes connections.

SEBA wins a contract supporting SAMHSA providing OMB Circular A-123 Review and Auditing Services. SEBA establishes and maintains internal financial controls.

SEBA wins a contract to evaluate NIH's Office of Patient Recruitment Call Center

2011
Business Development

2016
Won 1st & 2nd HHS Contracts

2018
Won our 3rd HHS Contract

2019
Won our 4th & 5th HHS Contracts

2020
Won our 6th HHS Contract

2021
Present Day

SEBA wins two contracts in July weeks apart. The first one is Patient Transport Services for NIH and the Patient Library Services for NIH's Clinical Center.

SEBA wins a contract supporting CMS providing Quality Written Correspondence and Quality Call Monitoring & a subcontract providing NIH Loading Dock Services

SEBA is presenting today as an HHS small business success story and looking for more ways to support HHS

SEBA
PROFESSIONAL SERVICES, LLC

Our successes & lessons learned

SEBA's Successes…	Lessons Learned…
Consistent and Excellent Performance	Invest More in Business Development
Building Strong Client Relationships	Utilize our IDIQ/GWAC Schedules
Teaming with other businesses	Pursue more certifications such as CMMI and ISO

SEBA
PROFESSIONAL SERVICES, LLC

Success Tips

Be Ready! – Plan for success, build on your success and be responsive

Knowledge – Leverage the best knowledge and capabilities you have

Recruit and Retain High Quality Staff and Experts – High quality employees are the key to your success. Be respectful, supportive, and treat them fairly.

Diversification vs. Single Focus – Its up to you! Focus on what works for your business and not what everyone else is doing.

Invest in Business Development – Get the support you need

Networking – Be purposeful about your networking efforts

Utilize Teaming and Relationships – Take the opportunities to build teaming relationships and be a good partner

Contact Us

Interested in working with SEBA? Contact us at:

www.sebapro.com

Or reach out directly to a BD resource below at*:*

Erhiuvie Abu, President and CEO

T: (202) 552-7356

eabu@sebapro.com

Meghan Mitchell, BD & Proposal Specialist

meghan.mitchell@sebapro.com