U.S. FOOD & DRUG ADMINISTRATION

Welcome to the FDA FISCAL YEAR 2024 SMALL BUSINESS FAIR

November 15, 2023

U.S. FOOD & DRUG ADMINISTRATION

Welcome

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
  - 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 (Natasha Boyce) to support access to federal contracting opportunities within the FDA**
  - HHS OSDBU Small Business Customer Experience (SBCX) **-** https://mysbcx.hhs.gov
  - Actions go through our Small Business Specialist, Natasha Boyce, 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**)

OAGS Contact Information

- Ron Loube, Associate Director, 240-402-7539 / ronald.loube@fda.hhs.gov
- Andrew Jernell, Director, Division of Information Technology Acquisitions (DITA) [All IT]
  240-402-0742 / andrew.jernell@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
- 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 Services (BAA)]
  240-402-7576 / vidya.vish@fda.hhs.gov
- Bryan Jones, Director, Division of Systems, Policy, and Program Support (DPSPS)
  240-402-7571 / bryan.jones@fda.hhs.gov
- **Natasha Boyce, FDA Small Business Specialist, 301-796-3145, natasha.boyce@hhs.gov**
- **New SBS after December, Cynthia Anderson, cynthia.Anderson@hhs.gov**

U.S. FOOD & DRUG ADMINISTRATION

THANK YOU FOR ATTENDING
FDA Small Business Vendor Fair

U.S. FOOD & DRUG ADMINISTRATION

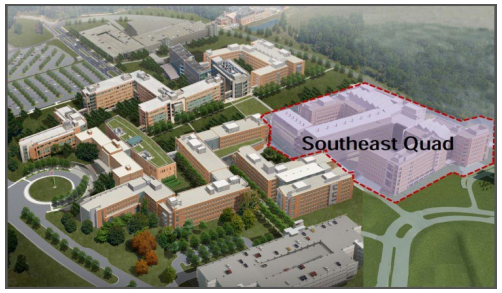
Opening Remarks

Benjamin Moncarz
Chief Financial Officer
Food & Drug Administration

Center for Biologic Evaluation and Research (CBER) Overview

Presented by: Lisa Portner, Branch Chief & Niquwana Bullock, Acquisition Liaison

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: Increase nation's preparedness to address threats

Goal 2: Improve global public health through international collaboration

Goal 3: Utilize advances in science and technology to facilitate development of safe and effective biological products

Goal 4: Ensure Safety of biological products

Goal 5: Advance regulatory science & research

Goal 6: Manage for organizational excellence and 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).

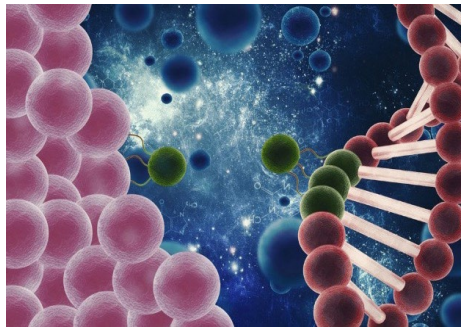
- FDA regulates $1 trillion worth of products a year, approximately $0.24 of every dollar spent in the U.S.





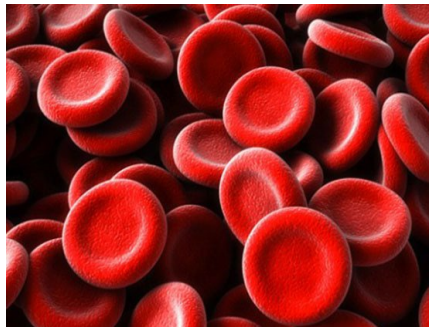


CBER Regulates Complex Products

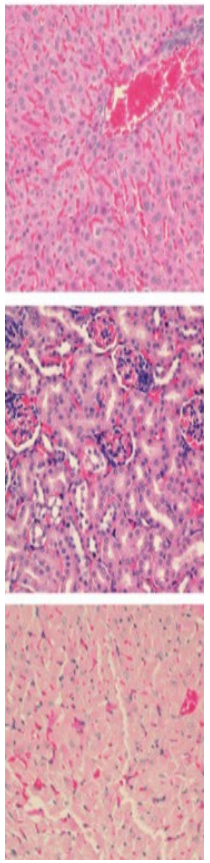


Cell & Gene Therapies

Vaccines: Preventive & Therapeutic



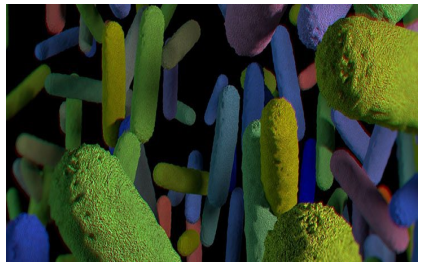
Blood, Blood Components & Derivatives



Tissues

Related Devices

Allergenic Products



Live Biotherapeutics

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

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

Top 10 Small Business Product Service Codes

Sum of Count			
Product Code Description	**2022**	**2023**	**Grand Total**
IT AND TELECOM - APPLICATION DEVELOPMENT SOFTWARE (LICENSE SOFTWARE)	8	4	**12**
IT AND TELECOM - BUSINESS APPLICATION SOFTWARE (LICENSE SOFTWARE)	6		**6**
IT AND TELECOM - BUSINESS APPLICATION/APPLICATION DEVELOPMENT SUPPORT SERVICES (LABOR)		5	**5**
LABORATORY EQUIPMENT AND SUPPLIES	63	42	**105**
MAINT/REPAIR/REBUILD OF EQUIPMENT- INSTRUMENTS AND LABORATORY EQUIPMENT	34	11	**45**
MEDICAL- OTHER	5		**5**
SPECIAL STUDIES/ANALYSIS- SCIENTIFIC DATA	9	9	**18**
SUPPORT- ADMINISTRATIVE: TRANSLATION AND INTERPRETING		4	**4**
SUPPORT- MANAGEMENT: OTHER	10	11	**21**
SUPPORT- PROFESSIONAL: OPERATIONS RESEARCH/QUANTITATIVE ANALYSIS	17	7	**24**
SUPPORT- PROFESSIONAL: OTHER	67	45	**112**
SUPPORT- PROFESSIONAL: VETERINARY/ANIMAL CARE	11	13	**24**
Grand Total	**230**	**151**	**381**

Small Business Contract Awards FY22 & FY23

QUESTIONS

CENTER FOR DRUG EVALUATION RESEARCH: OFFICE OF STRATEGIC PROGRAMS

DR. JOSE GALVEZ

ABOUT OSP

The Office of Strategic Programs (OSP) serves the Center Director, and the super office directors who lead major operations involved in regulatory oversight of human drugs. OSP's functional capabilities include strategic planning and management, negotiation with major external stakeholders over future work commitments and resource commitments, and process and program design and management.

WHAT WE DO

- Lead Center-wide strategic and **operational planning, performance analysis, and implementation**.
- **Steer CDER-wide technological advancements** and initiatives by evaluating existing data and analytic systems, canvassing innovation in data management systems, leading implementation of new IT portfolios, and managing CDER's IT budget.
- **Promote regulatory data standardization and harmonization** in collaboration with other FDA offices, domestic and international regulatory bodies, and other standard setting organizations to increase efficiency and sharing of key data elements to make swift regulatory decisions.
- Conduct and **maintain official CDER regulatory data** for internal and external analysis, communications, and official reporting.
- Serve as an **internal consulting service** to provide programmatic support, measure and conduct performance analysis, establish consistent best practices, and implement key initiatives.

FY 24 PRIORITIES

- Enterprise data management
- Harmonize workflow processes
- Generative AI capability

THANK YOU

Office of Surveillance and Epidemiology (OSE)

Regulatory Science Staff (RSS)

Center for Drug Evaluation and Research (CDER)

Regulatory Science Staff – What We Do

Advance regulatory science and enhance public safety by providing the scientific underpinnings required to inform regulatory decision-making

- Manage drug safety surveillance and research programs
- Lead the identification evaluation and development of new data sources, tools and methods to assess product safety
- Support the scientific operations by managing the extramural budget and acquisition of data sources, tools and associated services throughout their acquisitions' lifecycle

About OSE

Office of Surveillance and Epidemiology (OSE)

- Immediate Office (IO)
- Outreach and Communications Team (OCT)
- Organization Development (OD)
- Program Management and Analysis Staff (PMAS)
- Project Management Staff (PMS)
- Regulatory Affair Staff (RAS)
- Regulatory Science Staff (RSS)

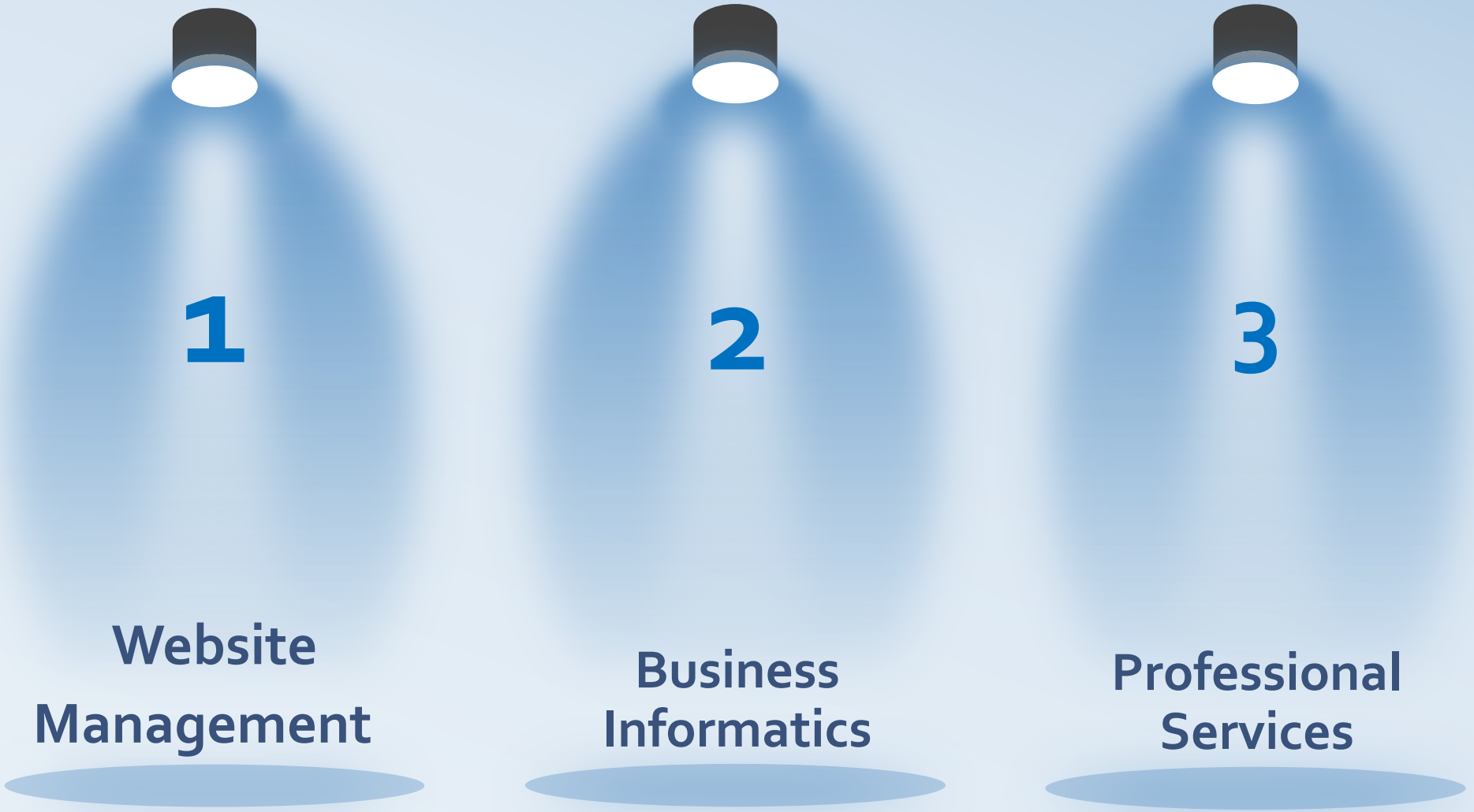
Sub-office: Office of Pharmacovigilance and Epidemiology (OPE)

- Division of Epidemiology
- Division of Pharmacovigilance

Sub-office: Office of Medication Error Prevention and Risk Management (OMEPRM)

- Division of medication Error Prevention and Analysis (DMEPA)
- Division of Mitigation Assessment and Medication Error Surveillance (DMAMES)

POTENTIAL OPPORTUNITIES FOR SMALL BUSINESSES



Requirement Details

Website Management

- NAICS Code: 541512-17 - Website Design Service
- NAICS Code: 561110-21 - Internet Management & Maintenance

Business Informatics

- NAICS Code: 541512 - Computer Systems Design Services
- NAICS Code: 541511 - Custom Computer Programming Services

Professional Services

- NAICS Code: : 541690 - Other Scientific and Technical Consulting Services
- NAICS Code: 541690-04 - Expertise & Technical Analysis
- NAICS Code: 541611 - Administrative Management and General Management Consulting Services

- **Development and Operations and Maintenance** (posting program and scientific content)
- **Knowledge Management** (workflow, tracking, reporting, collaboration, secure access portal)
- **Health Science Technical Support** (program/project management, medical writing, safety data analysis)

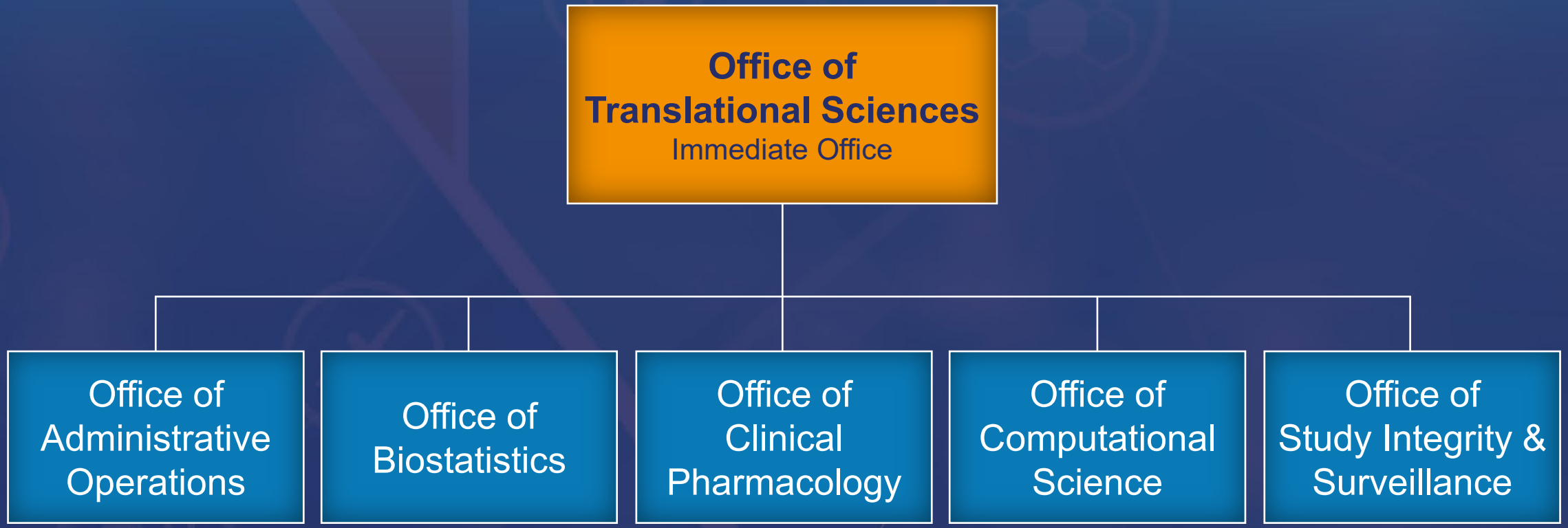
Office of Translational Sciences

Isaac Chang

11/15/2023

FDA U.S. FOOD & DRUG ADMINISTRATION

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

Sources: Who We Are (sharepoint.com)
https://fda.sharepoint.com/sites/insideFDA-CDER-OTS/SitePages/OTS-Who-We-Are.aspx

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 FY24 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

Center for Devices and Radiological Health (CDRH)

Small Business Fair

November 2023

CDRH

Our Mission

Protect and promote the public health.

Assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.

Provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee.

Facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

CDRH

Our Vision

To quickly identify poorly performing devices, accurately characterize real-world performance, and facilitate device approval or clearance.

Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.

Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

Center for Devices and Radiological Health (CDRH) Strategic Priorities

- Promote a Modern and Diverse Workforce

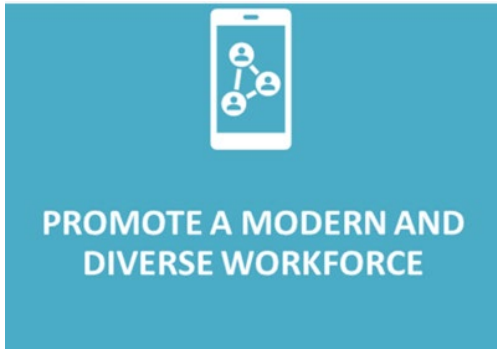
  A modern and diverse workforce prepares us for the future, while maximizing work-life balance and flexibilities, promoting creativity, enhancing diversity, and supporting a culture of trust and empowerment.

- Advance Health Equity

  To establish CDRH as a leader in advancing health equity by engaging with patients, healthcare providers, industry, and payers to advance knowledge and solutions across the total product lifecycle.

- Enhance Organizational Agility and Resilience

  CDRH will focus on rapidly adapting and effectively addressing current and anticipated changes and challenges to avoid disrupting the operations of the Center, as well as the work-life balance and wellness of our employees.

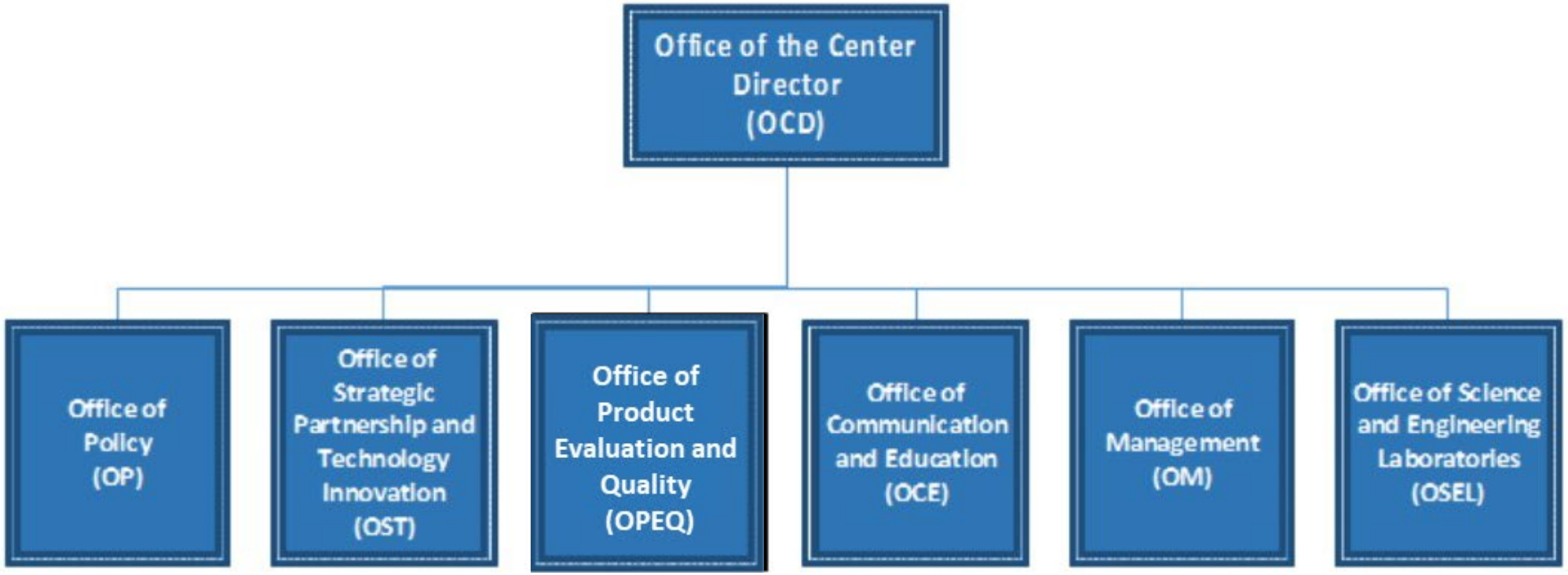


CDRH

Our Shared Values

- **Public Health Focus** - We focus on activities and outcomes that protect and promote public health.
- **Science-Based Decisions** - We make decisions based on sound science using the best available data, methods, information, and tools. We value and consider differing internal and external perspectives.
- **Our People** - Our staff is our most critical resource. We value individual excellence, teamwork, and personal and professional diversity.
- **Innovation** - We challenge the status quo and ourselves to foster positive change. We harness the creativity of our staff and stakeholders. We rapidly test and adopt new approaches to more effectively and efficiently accomplish our mission.
- **Transparency** - We foster public trust and predictability by providing meaningful and timely information about the products we regulate and the decisions we make.
- **Honesty and Integrity** - We maintain the public trust by acting with integrity and honesty. Our actions adhere to the highest ethical standards and the law.
- **Accountability** - We hold ourselves accountable for the actions we do and do not take. We acknowledge our errors and learn from them.

Center for Devices and Radiological Health (CDRH) Organizational Structure Overview



Center for Devices and Radiological Health (CDRH) Examples of what CDRH Regulates

- Dental Floss
- Toothbrushes
- Bandages
- Needles Catheters
- Contact Lenses
- Artificial Heart Valves
- Defibrillators
- Early Indictor Sepsis Devices
- Diagnostics Tests- Influenza, COVID

Center for Devices and Radiological Health (CDRH)
FY 24 Selected Programs of Interest

Office of Product Evaluation and Quality (OPEQ)

- Artificial Intelligence
- Medical Technologies (MedTech)
- Combating Antibiotic Resistant Bacteria Initiatives (CARBi)
- Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD)
- Over-the-Counter/Point-of-Care (OTC/POC)
- Fully Integrated Records Facility (FIRF)

Center for Devices and Radiological Health (CDRH)
FY 24 Selected Programs of Interest

Office of Strategic Partnerships and Technology Innovation (OST)

- Supply Chain
- Cybersecurity
- Digital Transformation
- Digital Health

Office of Science and Engineering Laboratories (OSEL)

- Lab Research Equipment

Center for Devices and Radiological Health (CDRH)
CDRH Resources

More on CDRH Offices and their Programs: CDRH Offices | FDA

North American Industry Classification System (NAICS)Codes

Commonly used CDRH NAICS Codes:

237130	334513	423430	511210	541380	541618	541720	561990	811219
238210	334515	423450	512110	541511	541690	541890	562112	811310
333298	334516	423490	518210	541512	541711	541990	611430	811412
333912	334519	423610	519190	541513	541713	561410	611699	813920
334118	337214	423690	541199	541519	541714	561499	711110	921190
334511	339112	423830	541330	541612	541715	561920	811211	923120

THANK YOU!

FDA Small Business Fair

Center for Food Safety and Nutrition (CFSAN)

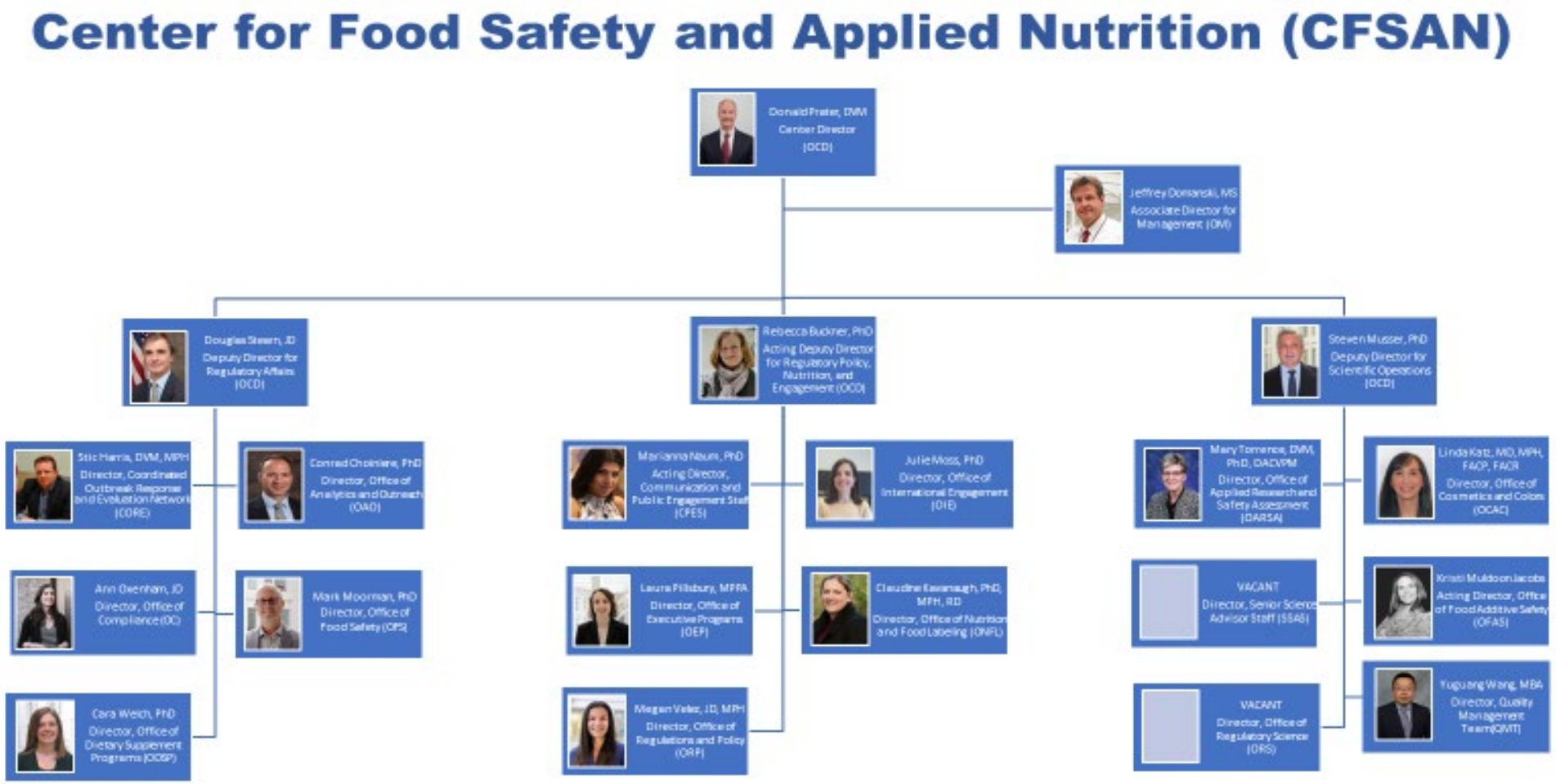
Brandon R. Jones

November 15, 2023

CFSAN's 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.

CFSAN's Organization



CFSAN's 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

Types of Acquisition Services and Supplies

- Scientific Support Services
- Facility Support Services
- Information Technology Services
- Professional Training Services
- Office Equipment and Maintenance
- Management Consulting Services

CFSAN: FY24 Opportunity

Project Title: "Support Services for CFSAN's Acquisition Liaison Branch"

Requirement Description: The objective of this contract is to obtain project management and acquisition support services to assist CFSAN's Acquisition Liaison Branch with managing the Center' contracts, interagency agreements, cooperative agreements and grants.

Current Award Detail:

- ✓ Current Contract Number: 75F40119C10031
- ✓ Current Contract Expiration Date: 03/08/2024

Advance Procurement Plan Details:

NAICS	561990
Estimated Project Value	*>= $1.5M and < $3M*
Center/Office Point of Contact(s)	CFSAN / LaQuia S. Geathers, laquia.geathers@fda.hhs.gov

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

THE PUBLIC HEALTH REALITY

The burden of cigarette smoking in the U.S.

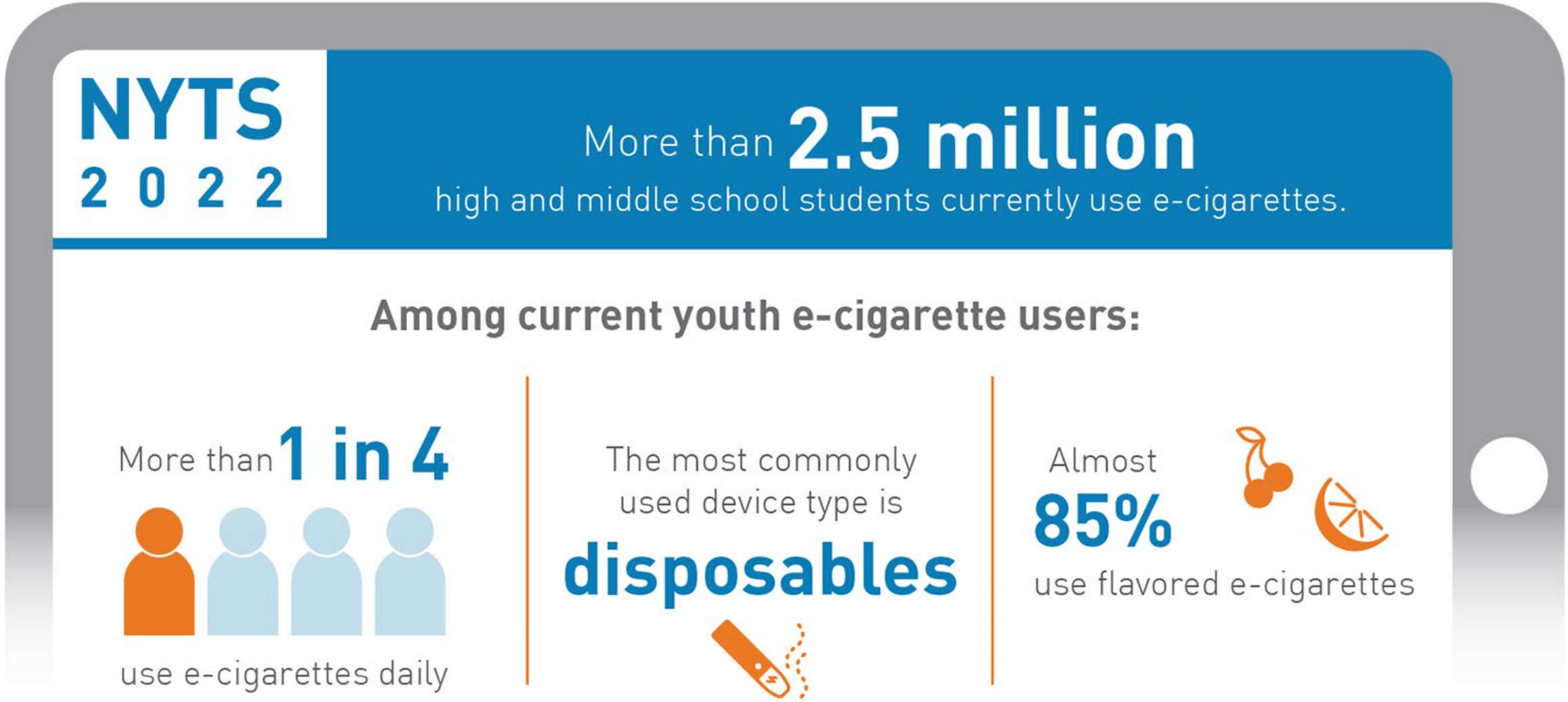
For Adults:

- Tobacco use is still the leading cause of preventable death – over 480,000 Americans die each year
- Nearly 70% of current adult smokers want to stop smoking completely
- In the past year, 55% of adult smokers made a quit attempt but only 7% were successful in quitting for 3-6 months

For Teens:

- Over 1500 youth under age 18 smoke their first cigarette every day
- Almost 90 percent of adult smokers started smoking before the age of 18

2022 NYTS FINDINGs: Youth E-cigarette Use



CTP OVERVIEW

Vision and Mission

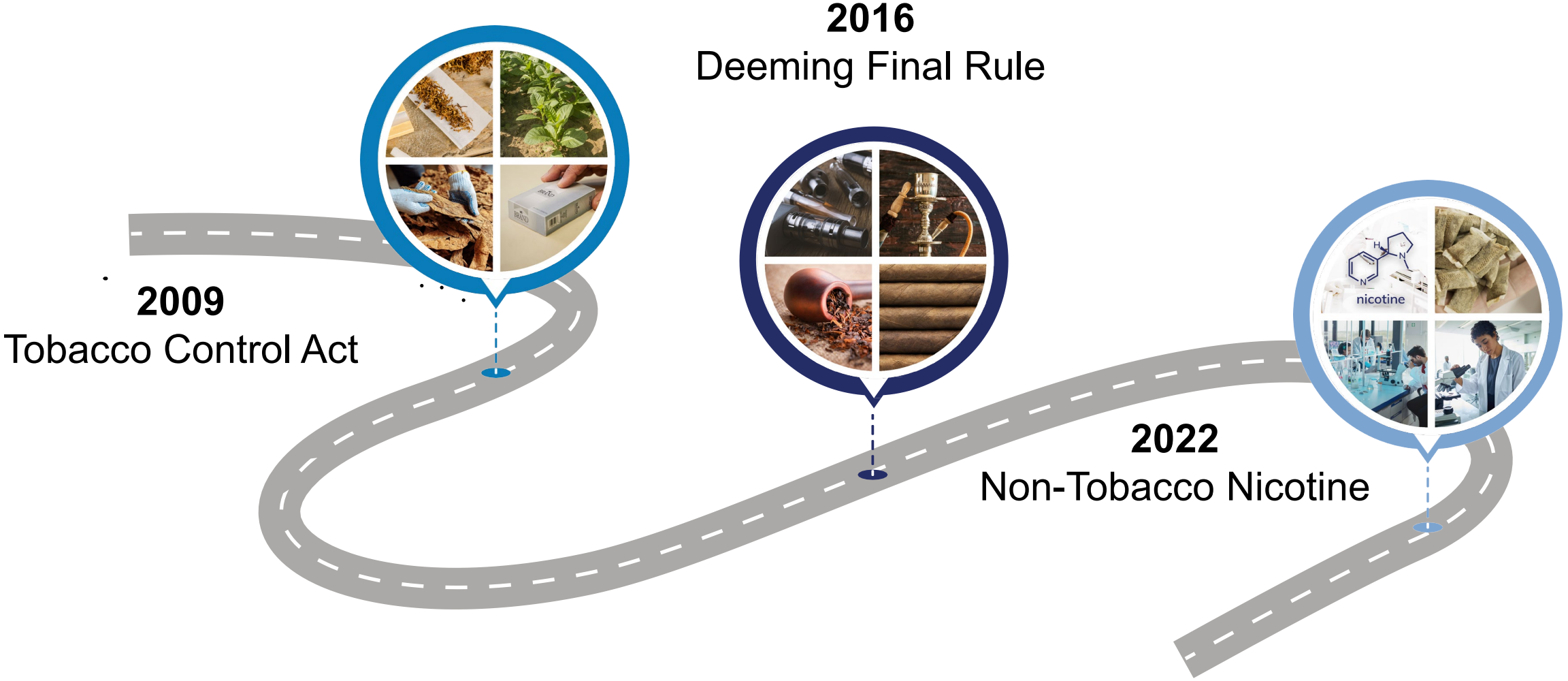
Vision

To make tobacco-related disease and death part of America's past, not America's future, and, by doing so, ensure a healthier life for every family.

Mission

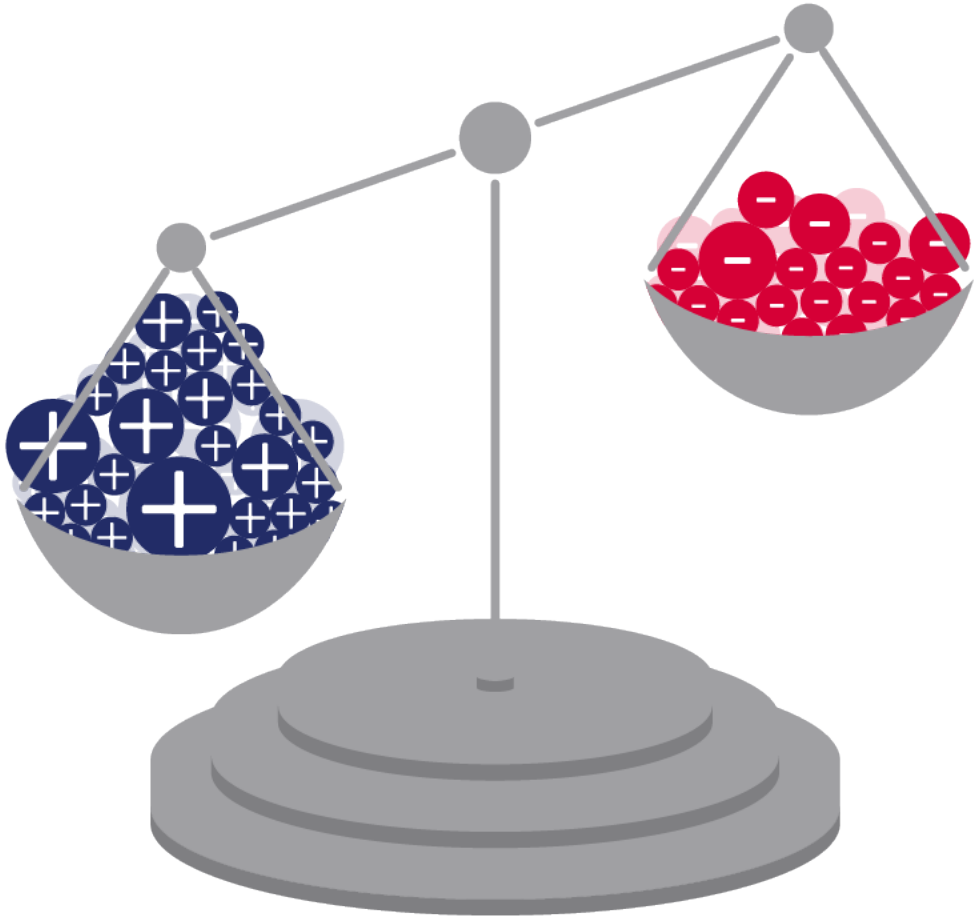
To protect Americans from tobacco-related disease and death by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

Tobacco regulation in the United States



Public Health Standard

- CTP pursues a “public health” standard as tobacco cannot be regulated using FDA’s traditional “safe and effective” standard
- Take into account the effects on both users and non-users of tobacco products
- Assess the “net” population-level health impacts of tobacco products



The Tobacco Control Act Authorities

CTP Authorities include:

- Premarket review
- Post-market surveillance
- Product standards
- Ingredients testing & reporting
- HPHC reporting
- Adverse event reporting
- New warning labels
- Advertising and promotion restrictions
- User fees

CTP Authorities generally DO NOT include:

- Setting tobacco tax rates
- Regulating therapeutic products (NRT)
- Setting clean indoor air policies
- Regulating tobacco growing
- Changing the minimum age to purchase tobacco products
- Requiring the reduction of nicotine yields to zero
- Providing cessation services
- Banning all tobacco products

FDA's Tobacco Regulatory Activities

CTP: FY24 Opportunity

Project Title: CTP-OHCE-24-C-0404 - Web Application Development and Database Management (IT)

Requirement Description: FDA/CTP has a requirement for technical services to support the operation and maintenance of the campaign web sites, and web application tools. Technical service activities include design, development, security, testing and evaluation, and operations and maintenance as well as project management to facilitate consistent and effective planning, development, implementation, monitoring, and optimization of all campaign websites and web application tools. In addition, FDA/CTP intends on migrating the campaign websites and web application tools from the DHHS domain to FDA. Migration services (Optional Task) would include system installation, server environment configuration, and maintenance support

Current Award Detail:

- ✓ Current Contract Number (If applicable): 75F40120F80021
- ✓ Current Contract Expiration Date: 5/31/2024

Advance Procurement Plan Details:

NAICS	541511 – Custom Computer Programming Services
Estimated Project Value	*>= $1.5M and < $3M*
Center/Office Point of Contact(s)	Allison Mlawsky(Contract Specialist) – Allison.Mlawsky@fda.hhs.gov

CTP: FY24 Opportunity

Project Title: CTP-OS-24-C-0735 - CTP Content and Case Management System Licenses

Requirement Description: provide FDA's Center for Tobacco Products (CTP) OpenText Platform or Equal to implement CTP's Rhapsody System for case and content management. Within CTP's requirement the following services are required through the OpenText (or Equal):

- OpenText Platform Licenses
- OpenText Product Training
- OpenText Prime Protect Support
- OpenText Professional Services

Current Award Detail:

- ✓ Current Contract Number (If applicable): 75F40122F80046
- ✓ Current Contract Expiration Date: 02/04/2024

Advance Procurement Plan Details:

NAICS	511210 – Software Publishers; 541618 – Other Management Consulting Services
Estimated Project Value	*>= $1.5M and < $3M*
Center/Office Point of Contact(s)	Alicia Baltimore(Contract Specialist) – Alicia.Baltimore@fda.hhs.gov

CTP: FY24 Opportunity

Project Title: CTP-OCE-24-C-7246: Tobacco Retailer Compliance Inspections Region 1 IDIQ Northeast

Requirement Description: this IDIQ contract is to conduct inspections of tobacco product retailers to gather evidence of and document any potential violations of applicable provisions of the FD&C Act and its implementing regulations, and to provide related support services to FDA during enforcement actions based upon the evidence gathered during such inspections. FDA will utilize the information and evidence obtained during inspections to determine whether retailers violated any applicable requirements and to pursue enforcement actions. This includes the following states: Connecticut, Delaware, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont.

Current Award Detail:

- ✓ Current Contract Number (If applicable): 75F40119D10036
- ✓ Current Contract Expiration Date: 9/29/2024

Advance Procurement Plan Details:

NAICS	923120 – Administration of Public Health programs
Estimated Project Value	>= $20M and < $50M
Center/Office Point of Contact(s)	Madeline Bryant (Contract Specialist) – madeline.bryant@fda.hhs.gov

CTP: FY24 Opportunity

Project Title: CTP-OS-24-C-0781 - In Vivo and In Vitro Study 1

Requirement Description: The objectives of this contract are to develop an aerosol co-exposure system for use with a human relevant in vitro air-liquid interface (ALI) airway tissue model, to characterize the occurrence of cytotoxic and genotoxic responses following exposure to single and combined aldehydes, and to assess the occurrence of enhanced cytotoxic and genotoxic responses following co-exposure to this aldehyde mixture to identify if toxic interactions between these HPHCs occur.

Current Award Detail:

- ✓ Current Contract Number (If applicable): 75F40123C00215
- ✓ Current Contract Expiration Date: N/A

Advance Procurement Plan Details:

NAICS	541990 – All Other Professional, Scientific, and Technical Services
Estimated Project Value	*>= $1.5M and < $3M*
Center/Office Point of Contact(s)	Michele Jackson (Contract Specialist) – Michele.Jackson@fda.hhs.gov

Center for Veterinary Medicine: Mission and Opportunities

Arnel Peralta
Office of Surveillance and Compliance
FDA, Center for Veterinary Medicine

CVM Mission

The mission of the U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) is to protect human and animal health.

FDA CVM FY2024 Priorities

- CVM is committed to providing the public with access to accurate, timely, and easy to understand information on regulated products, agency policies, and programs.

- Documents placed on FDA's website must be in compliance with Section 508 of the Rehabilitation Act of 1973, as amended.

- Section 508 requires that the government's electronic and information technology (EIT) is accessible to people with disabilities. Section 508 ensures that Federal employees with disabilities are able to use EIT to do their jobs. It also ensures private citizens with disabilities seeking information from Federal sources can utilize IT to access government information.

REQUIREMENTS

SECTION 508 REMEDIATION

- Provide remediation services for WORD, PDF, and Excel records, that may or may not contain redactions, and may or may not be images for Section 508 compliance

- Specific expertise is needed for 508 requirements in order to troubleshoot issues and create accessible documents to be compliant with FDA's standards.

- Remediate documents containing redactions, images, and those that are unable to apply Optical Character Recognition software

Questions????

Thank you.

U.S. FOOD & DRUG ADMINISTRATION

Office of Facilities Engineering and Mission Support Services (OFEMS)

FDA's Small Business Vendor Fair

November 15, 2023

Office Of Facilities Engineering and Mission Support Services

Mission

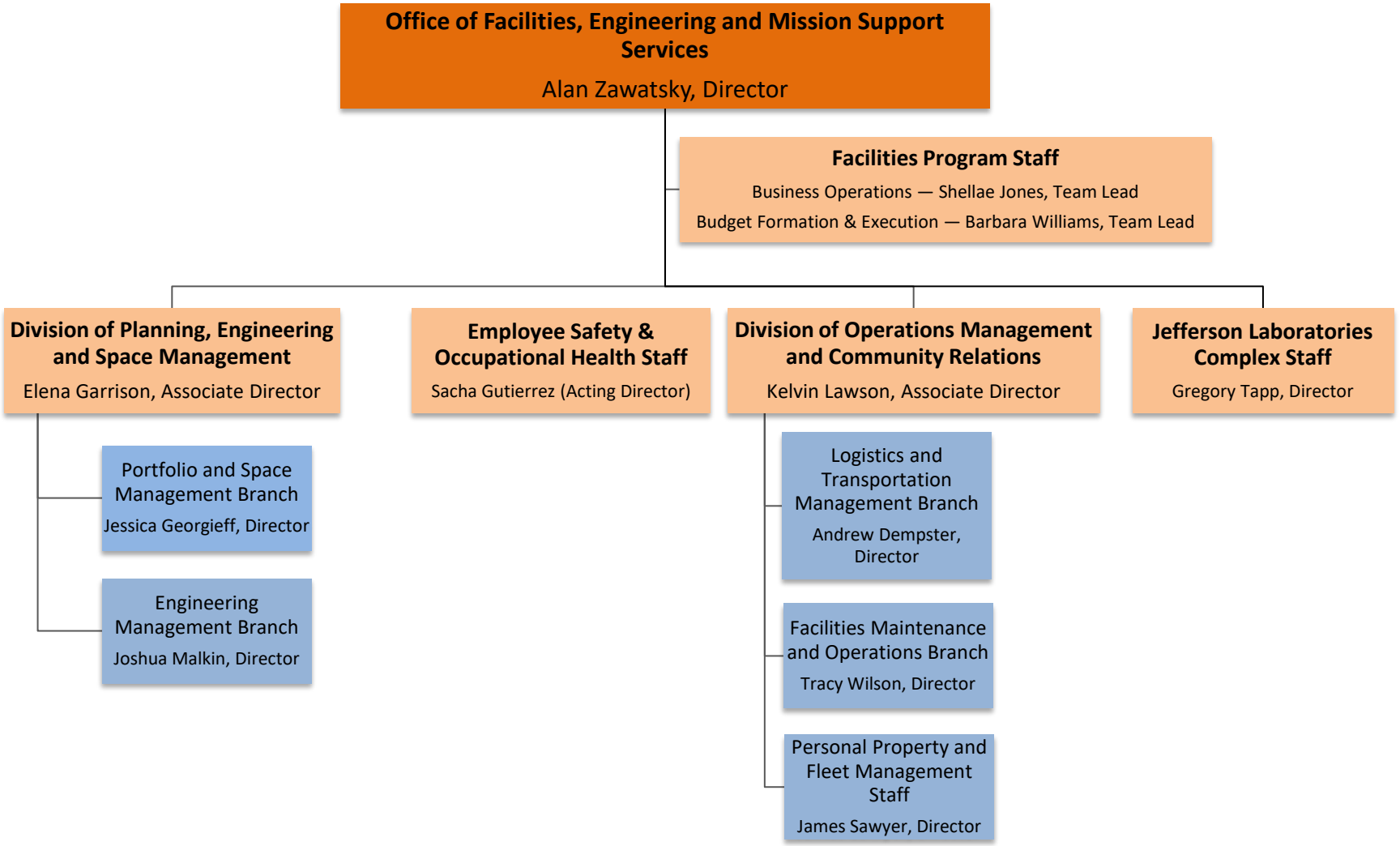
The mission of the Office of Facilities Engineering and Mission Support Services (OFEMS) is to create a high-quality work environment by providing vital facilities and mission support services to meet the needs of our customers and stakeholders nationwide.

Vision

OFEMS is a customer service organization enabling the FDA mission by creating and maintaining world-class facilities, providing support services to enhance synergy, productivity and quality of work life.

OFEMS creates a high-quality work environment by providing vital facilities and mission support services to meet the needs of its customers and stakeholders nationwide.

OFEMS Organization



OFEMS Staff

OFEMS staff is primarily located in the Washington metropolitan headquarters area;

However, we also provide support for all FDA locations across the nation, and have staff located in:

Dauphin Island, AL

Jefferson, AR

Irvine, CA

Atlanta, GA

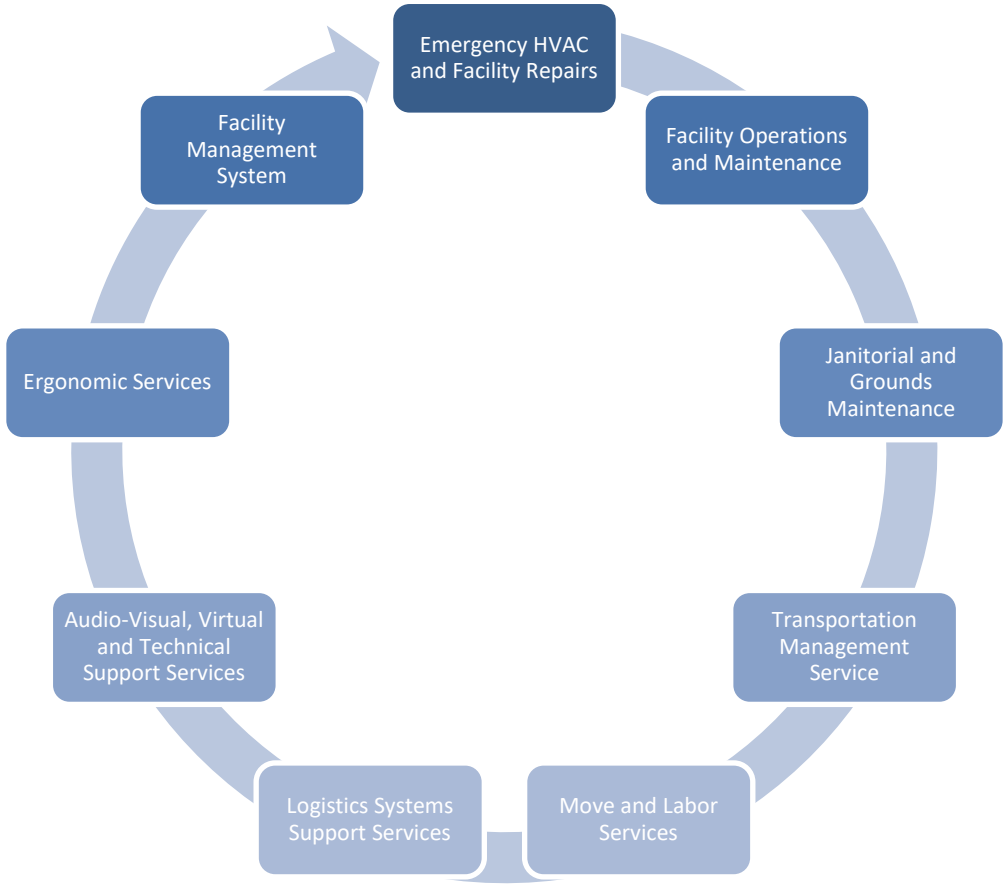
Boston, MA

San Juan, Puerto Rico

OFEMS Services

- Facilities Operations, Management and Oversight in Headquarters & Field Locations
- Jefferson Laboratories
- Logistics Services
- Safety and Occupational Health
- Planning, Engineering & Space Management
- Lease Management
- Sustainability Program
- Facility & Logistic Enterprise Systems
- Personal Property & Fleet Management

Type of Contract Purchases



FY2024 Upcoming Acquisitions Over $1 million Suitable for Small Business

- Transportation and Transit Services IDIQ
- Move and Labor Services IDIQ
- Logistics Systems IDIQ
- Facility Operation and Maintenance Contracts
- Occupational Medicine

OFEMS Acquisitions

- OFEMS Acquisition Statistics for FY2024 - Planned
  - Approximately 85 Contracts Tracked
    - Consists of service contracts for operations and maintenance, janitorial, pest, trash, move and labor, document shredding, transportation, parking, audio-visual and enterprise systems.
    - Approximate annual cost of the contracts is $54,000,000

- LTMB Acquisition Statistics for FY2023 - Executed
  - Approximately 39 Contracts Tracked
    - 5 of the 39 contracts tracked are 5-year continuous IDIQs
    - total 5-year contract authority of $224,023,831
    - 34 contracts processed; total value of $15,058,981

Thank you!

Office of Digital Transformation: Mission and Opportunities

Mahesh Choksi

November 15, 2023

ODT- Vision and Mission

Mission: Empower stakeholders to safeguard public health through high quality, secure technology, and data capabilities.

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

Organization: ODT is built upon three core values:

- **Accountability:** Holding yourself and others to stay true to our words and follow through on commitments
- **Empowerment:** Creating an environment for yourself and for others where everyone is able to share their ideas and knowledge and have the opportunities to grow their skills and responsibilities
- **Effective Execution:** Providing the highest level of quality in your work to provide value for customers and each other

Acquisition Strategies And Partnership (ASAP) Division

Goals:

The main goals of the Division are:

1. Develop an **Acquisition–as-a –Service (AaaS)** model for IT acquisitions that can be utilized across ODT
2. Manage **vendor partnerships** to improve efficiencies and drive cost down
3. Support **Small Business Vendors**
4. **Maximize value** of major IT acquisitions by seeking to control costs, manage risk, and support procurement decision-making

Main Objectives:

1. Consolidate ODT IT acquisitions
2. Develop agile acquisition processes
3. Develop strategic acquisitions to align with TMAP/DMAP strategic priorities
4. Develop, track, and report vendor performance
5. Develop a full-time COR program model, a staffing plan, and acquisitions workforce development
6. Develop new tools and procedures to track software entitlement, utilization, and compliance.

Acquisition Strategies And Partnership (ASAP) Division

ODT FY23 planned IT Acquisitions

Request Title	Total Contract Range
FY24 ChemDoodle Licenses	25K - 250K
FY24 ESG Akamai WAF & OPSWAT Licenses	25K - 250K
FY24 Solarwinds Maintenance	25K - 250K
FY24 Infoblox Hardware Maintenance	25K - 250K
FY24 Tableau Licenses Purchase (Mid Year)	25K - 250K
FY 24 BoxCloud	25K - 250K
NCTR APC UPS Maintenance	25K - 250K
FY24 ACS Nutanix G8 Maintenance Renewal	25K - 250K
FY24 Ivanti Licenses Renewal	25K - 250K
FY24 Knime Software Licenses and Maintenance	25K - 250K
FY24 Keyfactor Certificate Management System	25K - 250K
FY24 Pure Storage Evergreen Subscription	25K - 250K
FY24 Computer Accessories and Peripherals SEWP Order # 8	25K - 250K
FY24 Computer Accessories and Peripherals SEWP Order # 9	25K - 250K
FY24 Computer Accessories and Peripherals SEWP Order # 10	25K - 250K
FY24 UiPath Software Licenses and Maintenance	25K - 250K
FY24 Mailgate Software Maintenance	25K - 250K
FY24 AWS SCALR Licenses	25K - 250K
FY24 F5 Load Balancer Maintenance	25K - 250K
FY24 Neuvector Licenses Renewal	25K - 250K
FY24 Portworx Licenses Renewal	25K - 250K
FY24-FY28 PrecisionFDA Production Services IDIQ	30M- 50M
FDA Cloud contract to get AWS services	50M-100M

FDA IT Strategic Plan

FDA released IT Strategic Plan for FY24-FY27 focusing on technology, data, cybersecurity, enterprise transformation, and leadership. The plan is located here

Strategic Goals

The plan focuses on six key goals, including:

1. **Enhancing Collaboration:** Create a Shared OneFDA Ecosystem.
2. **Strengthening Infrastructure:** Modernize and secure IT infrastructure.
3. **Modernizing Services:** Optimize IT services for stability and adaptiveness.
4. **Sharing Data:** Drive efficiency and innovation.
5. **Adopting AI and Innovations:** Embrace emerging technologies.
6. **Cultivating Talent and Leadership:** Develop technology expertise and leadership.

2023 FDA Digital Transformation Symposium – Dec 4-7, 2023

The FDA.Gov page with the registration link: Register Here.

More than 1500 vendors joined last year. It is a hybrid- virtual and in person event.

Date: December 4 - 7, 2023

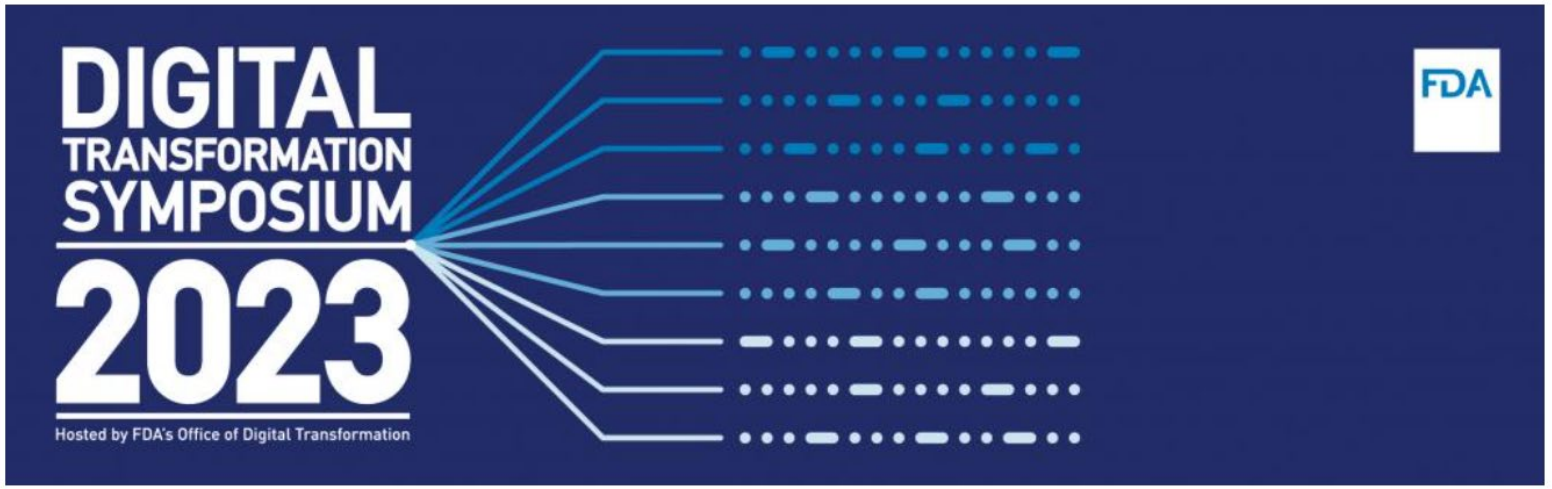
Sponsored By: Office of Digital Transformation

Day1: Mon, Dec 4 9:00 AM - 4:00 PM ET

Day2: Tue, Dec 5 9:00 AM - 4:00 PM ET

Day3: Wed, Dec 6 9:00 AM - 4:00 PM ET

Day4: Thu, Dec 7 9:00 AM - 4:00 PM ET



FDA's Office of Regulatory Affairs:
Protecting Consumers & Enhancing Public Health

Michelle Hawley
Division Director, Division of Contracts and Grants
November 15, 2023

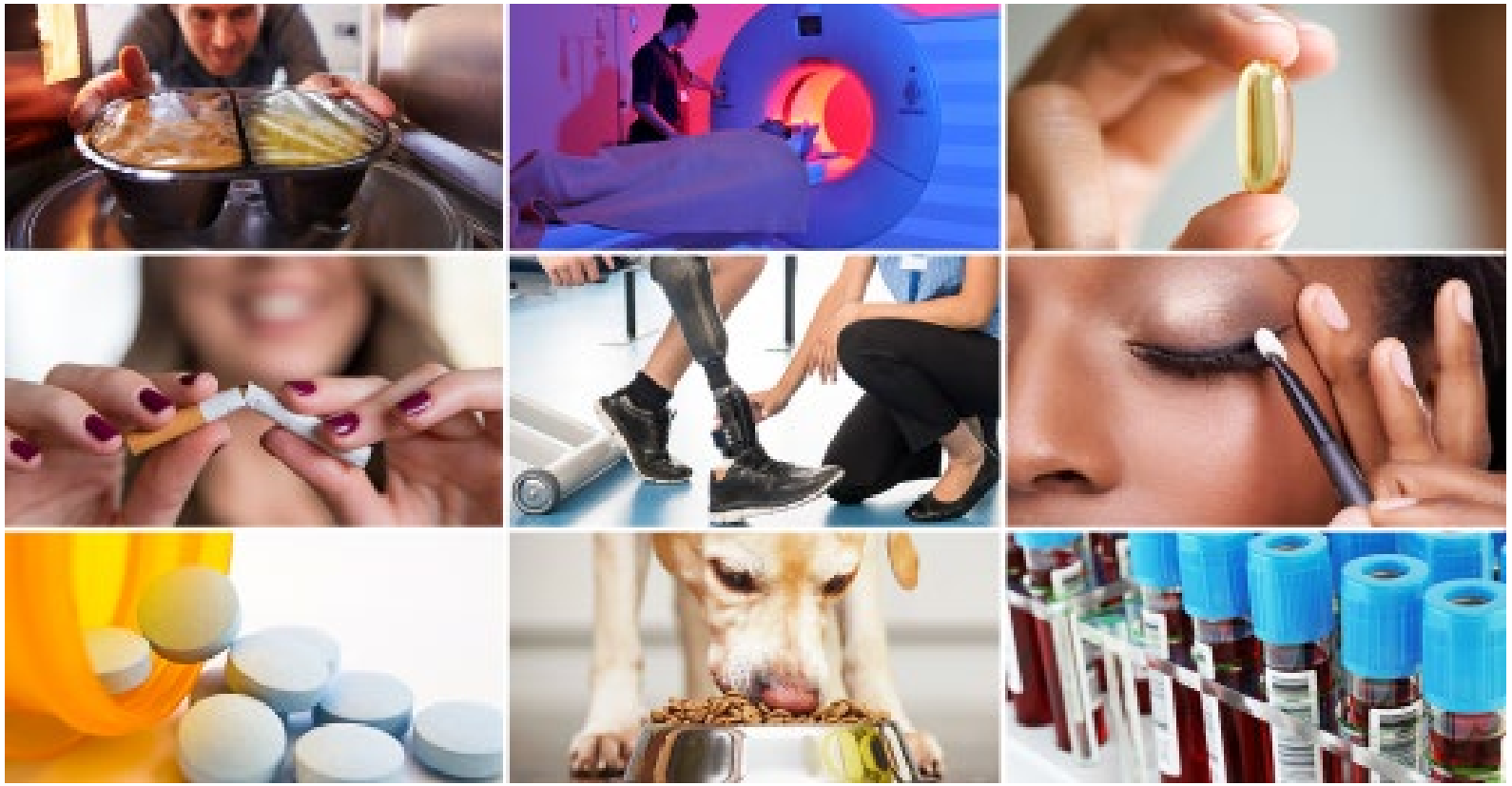
ORA Mission and Vision

Mission

Protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products

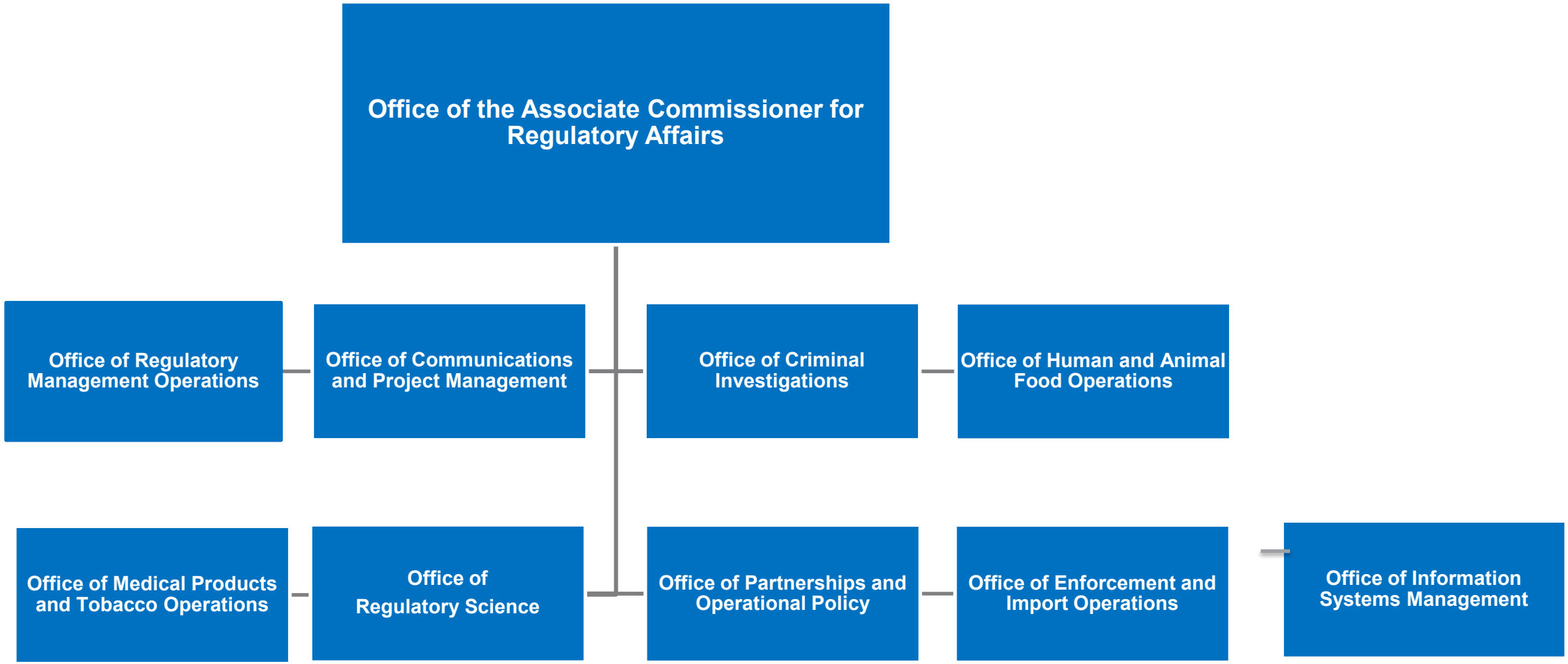
Vision

Public health is protected, promoted, and advanced



The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities.

ORA Organizational Structure



ORA Across the Country

ORA has 20 field district offices and 13 field laboratories across the continental United States and Puerto Rico.

Los Angeles District Office

PEOPLE OF ORA

NEARLY 5,000 EMPLOYEES

- Consumer Safety Officers
- Criminal Investigators
- Laboratory Analysts
- Administrative Management Specialists
- Communication Specialists

How ORA protects public health

- Conducts inspections of firms producing FDA-regulated products
- Investigates consumer complaints, emergencies and criminal activity
- Enforces industry compliance with regulations
- Collects samples for laboratory analysis
- Examines FDA-regulated products imported into the country

ORA conducts inspections in foreign countries and has offices in:

- China
- Europe: Brussels, Belgium and London
- Latin America: Costa Rica, Honduras, Mexico
- India

FY 2024 Priorities

- Strengthen the Workforce
- Align ORA Core Operations with FDA Operations
- Optimize Work Planning and Inspectional Processes
- Expand Collective Capability and Capacity of Regulatory Partners

QUESTIONS?

U.S. FOOD & DRUG ADMINISTRATION

Office of Acquisition and Grant Services Overview

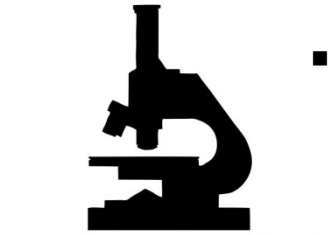
Bryan Jones
Director, Division of Policy, Systems, and Program Support

Agenda

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

The FDA Mission

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



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

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

- FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

OAGS Mission, Vision, & Goals

Mission

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

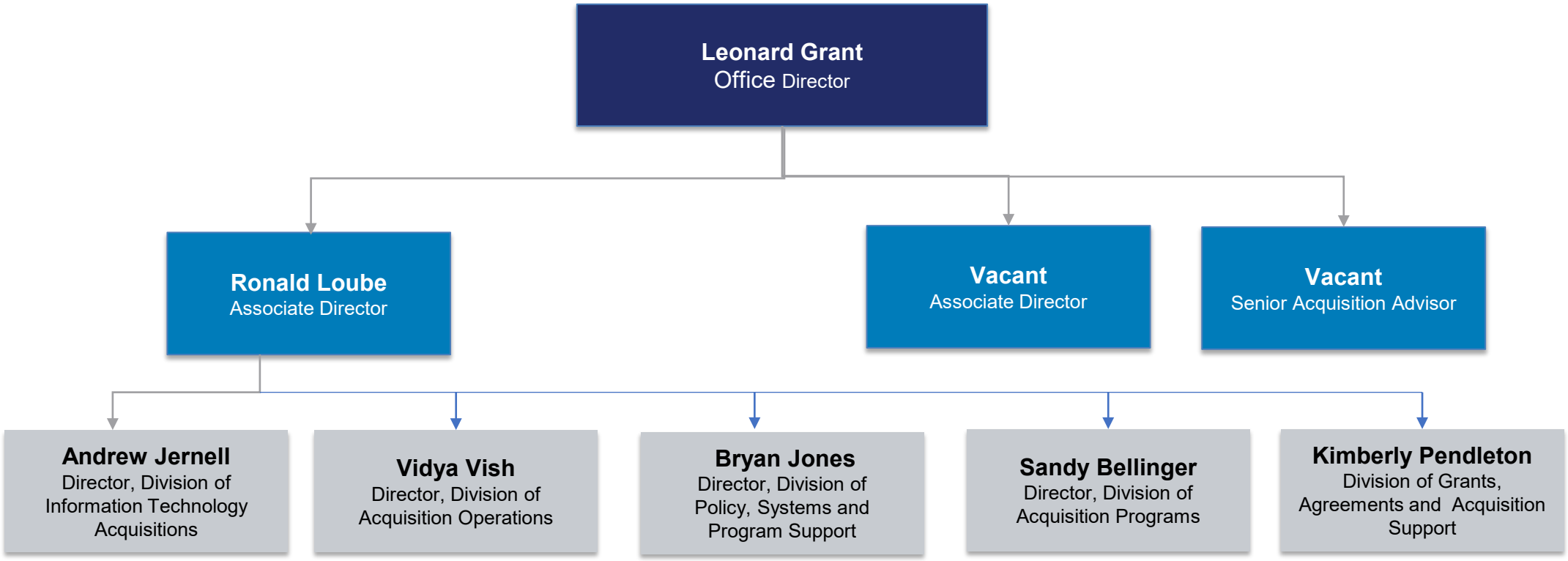
Vision

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

Goals

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

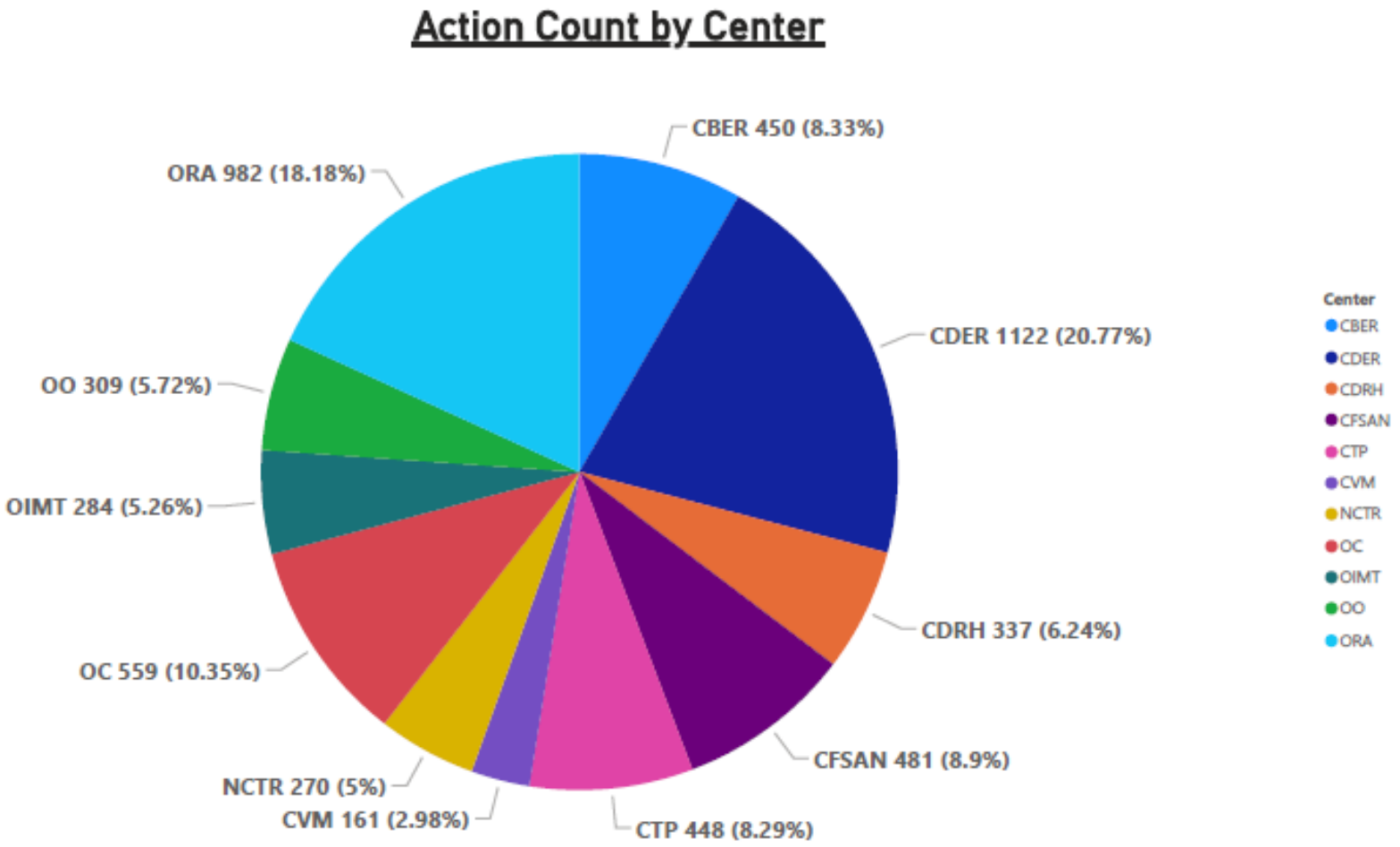
Organizational Structure



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

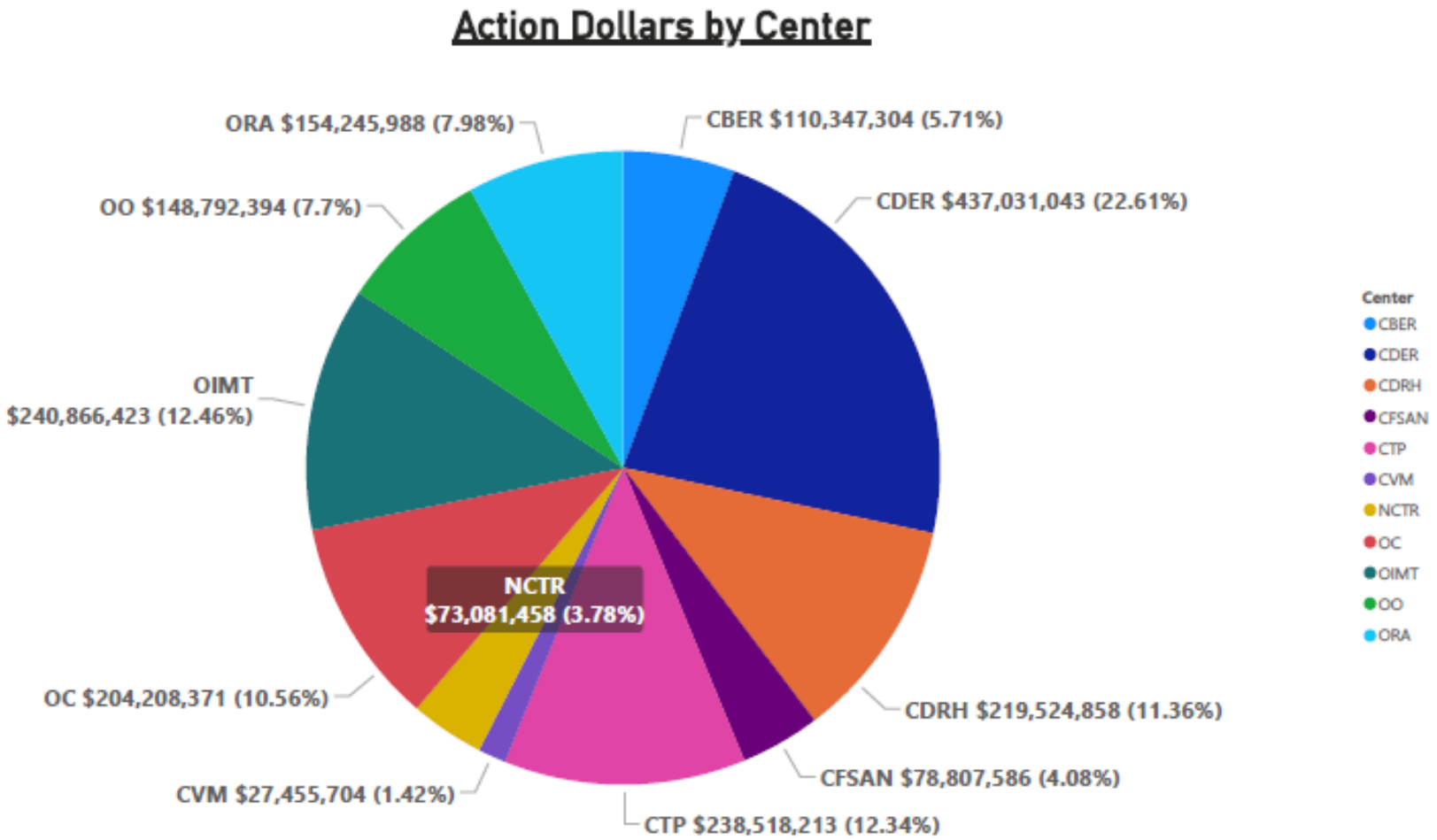
OFBAP | Office of Finance, Budget, Acquisitions, and Planning

FY23 Statistics for OAGS



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

FY23 Statistics for OAGS



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

Top 10 Contract Expenditure Categories for FY 2023

Top 10 Vendors

Vendor Name	Sum 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

NAICS	Dollars Obligated
CUSTOM COMPUTER PROGRAMMING SERVICES	$ 299,832,202.89
ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES	$ 267,879,063.23
COMPUTER SYSTEMS DESIGN SERVICES	$ 266,626,999.76
OTHER COMPUTER RELATED SERVICES	$ 203,476,980.63
ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	$ 144,452,853.99
ADVERTISING AGENCIES	$ 97,676,040.32
COMPUTING INFRASTRUCTURE PROVIDERS, DATA PROCESSING, WEB HOSTING, AND RELATED SERVICES	$ 91,118,793.55
RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY (EXCEPT NANOBIOTECHNOLOGY)	$ 79,906,499.25
ADMINISTRATION OF PUBLIC HEALTH PROGRAMS	$ 57,584,222.32
SOFTWARE PUBLISHERS	$ 53,155,330.79
Grand Total	**$ 1,561,708,986.73**

FDA Socioeconomic Goals

Small Business Award Categories	FY Goal (FY15-21)	FY16	FY17	FY18	FY19	FY20	FY21	FY 22 Goal (new)	FY22	FY23
Small Businesses	38%	48.5%	39.64%	36.8%	39.06%	40.09%	34.33%	37.09%	33.49%	38.02%
Small Disadvantaged Businesses	5.0%	27.9%	24.31%	25.0%	27.14%	26.96%	23.84%	25.20%	23.96%	25.84%
Women-Owned Small Businesses	5.0%	17.8%	14.22%	14.1%	14.13%	12.68%	10.33%	11.99%	11.01%	11.58%
HubZone Businesses	3.0%	2.0%	1.40%	1.8%	2.75%	4.09%	3.81%	4.94%	4.48%	4.99%
Service-Disabled Veteran Owned	3.0%	4.9%	3.42%	3.4%	2.81%	3.91%	2.29%	3.80%	3.22%	3.70%

In 2023, FDA awarded more than $727 Million to Small Businesses!

FDA FY23 Competition Data

	Actions Competed		
Category	Total Available for Competition excluding micro purchases	Competed	Competition Percentage
Total FDA	5,406	3,617	66.91%
HHS Target			65%

	Dollars Competed		
Category	Total Available for Competition excluding micro purchases	Competed	Competition Percentage
Total FDA	$ 1,932,878,529	$ 1,419,663,359	73.45%
HHS Target			75%

Note: FDA's State Inspection Programs is not available to be complete via Statutory Authority

Best Practices for Doing Business with FDA

Target your Engagement

- Focus on Primary NAICS codes and Consider Teaming
- Learn about FDA market and the goods and services it procures
- Read OFPP “Myth-Busting” Memorandums to improve engagement

Develop Allies

- Engage with FDA SB Specialist
- Participate in FDA and HHS outreach events

Own Your Future

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

Attendee Question: How and where does the FDA communicate its annual forecast? Are they updated quarterly, monthly or weekly?

- FDA Fiscal Year 2024 Forecast of Opportunities is posted here: SBCX (hhs.gov)
  - Updated by FDA for Fiscal Year 2024 in August 2023
  - Additional updates added in September 2023
- FDA is committed to updating the SBCX quarterly in Fiscal Year 2024

Attendee Question: How often does your website provide updates on low dollar value contracting opportunities and where can small businesses go to find them?

- FDA eBidBoard promotes awareness of and competition in business opportunities for contract actions with an anticipated value between $15,001 - $25,000.

- FDA eBidBoard | FDA

Attendee Question: What vehicles will FDA be using going forward? We would like to see FDA utilize GSA MAS more if possible.

FDA				
Spend Under Management Contract	**Tier**	**FY2021 Oblig.**	**FY2022 Oblig.**	**Delta**
SCHEDULE 70 - INFORMATION TECHNOLOGY	TIER 2	$219,891,494.08	$286,411,143.64	$66,519,649.56
PROFESSIONAL SERVICES SCHEDULE (PSS)	TIER 2	$210,300,195.57	$167,821,448.62	-$42,478,746.95
Sched 70 HW SW	BIC	$130,202,119.39	$140,168,789.48	$9,966,670.09
NASA SEWP	BIC	$115,456,148.40	$94,207,432.20	-$21,248,715.80
MAS	TIER 2	$52,772,483.39	$77,197,535.35	$24,425,051.96
NITAAC CIO SP3 Unrestricted	BIC	$59,735,957.83	$51,381,342.60	-$8,354,615.23
SCHEDULE 738X - HUMAN RESOURCES & EQUAL EMPLOYMENT OPPORTUNITY	TIER 2	$2,153,899.84	$28,820,020.53	$26,666,120.69
8(a) STARS III	BIC	$1,715,000.26	$28,818,916.12	$27,103,915.86
NITAAC-SP3 Small Business	BIC	$12,541,694.55	$25,737,680.45	$13,195,985.90

Source: GSA Data to Decisions Dashboard

U.S. FOOD & DRUG ADMINISTRATION

Additional Questions, as time permits.

U.S. FOOD & DRUG ADMINISTRATION

---ces---
Integrity At Work

Computer Evidence Specialists, LLC
Small Business Success Story

Carl Florez
President

Overview

- Who We Are- CES, LLC
- Ups & Downs of the Small Business World
- Challenges of Being a Small Business
- Successes as a Small Business
- Advice to Other Small Business
- Keys to Success as a Small Business

Computer Evidence Specialists, LLC

- VA verified SDVOSB, Minority-Owned SB founded in 2002
- Core Capabilities: Investigations, Intelligence, Compliance, Staffing, Training
- CES is dedicated to the highest degree of integrity, ethics, and professional conduct with a strong commitment to excellence
- Offices in Florida & Maryland
- Former 8(a)
- Contract Vehicles: GSA, SeaPort
- Clients: FDA, VA, CMS, USDA, Navy, DHS, etc

Computer Evidence Specialists, LLC

- Starting the Company
- Cyber Focus
- 4 Person Company
- First Government Contract
- Growth Over 20 Years

"Ups"

The Feel Good Stuff about Small Business

- Winning Contracts
- Subcontractor
  - Learn the Business of Small Business
- Prime
  - Implement the Business of Small Business

"Downs"

Frustrations of Small Business

- Dependence on Big Business
- Loss of Trusted Partners
  - Changes in Management
  - Changes in Finances
  - Changes in Focus
- Loss of a "know we are going to win this one" Bid
  - LPTA loss
  - Weak Proposal loss
  - Weak Team loss

Challenges

- Subcontracting
  - ‘One-Trick Pony’
- COVID/ Pandemic Impacts
  - Surviving the impact of Covid on financial status of company
  - PPT, LOC, Personal Loans
- Finding the Perfect Management Team
- Developing the Perfect BD Team and Process

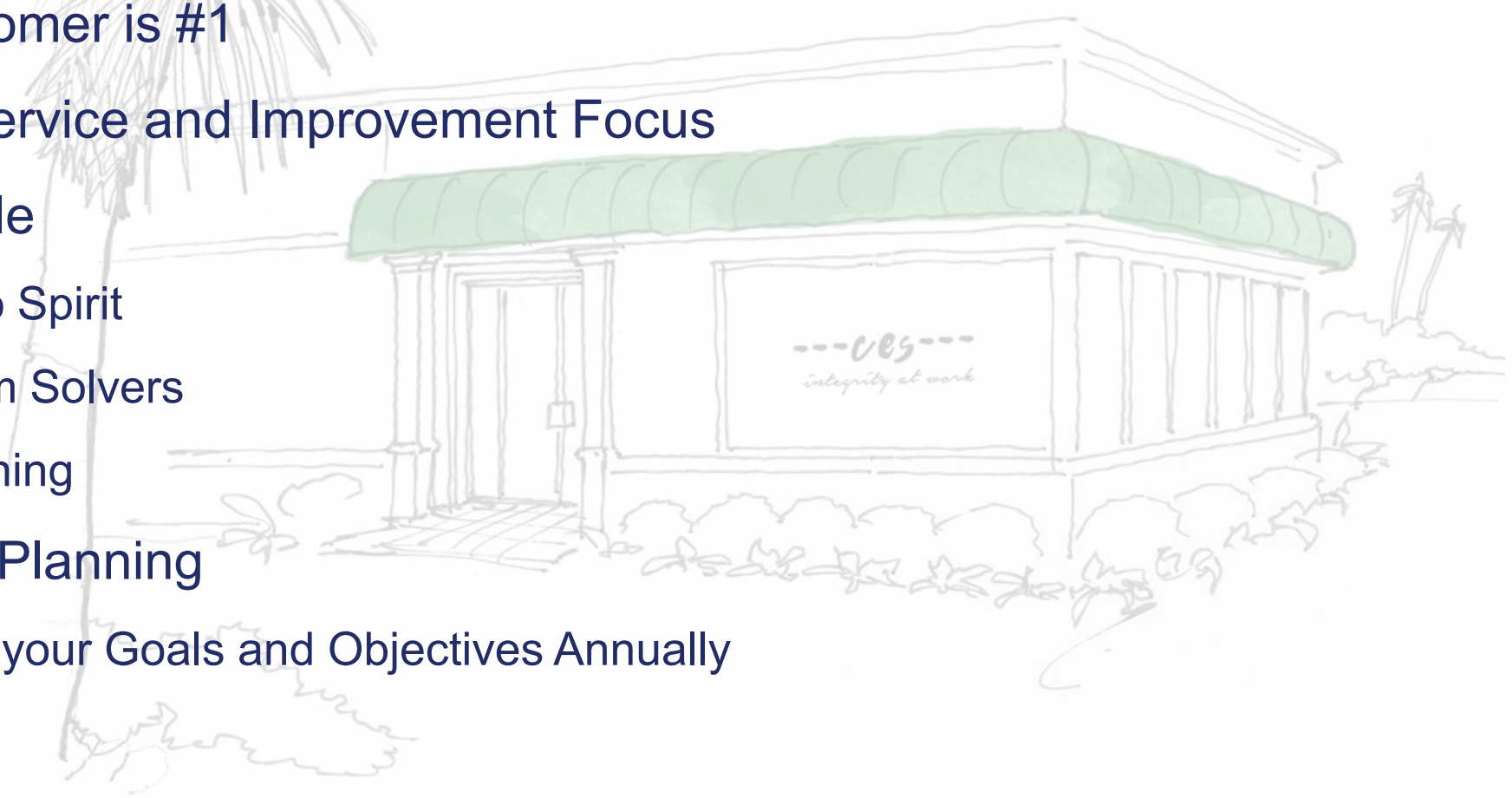
Successes

- Diversifying
  - Un-Subbing from a Single Prime
- Priming
  - Our First Win!
- Working “Making a Difference” Contracts
  - FDA CTP
  - Military Working Dogs
  - EEO
  - Medicare/Medicaid Fraud

Advice

Our Lessons Learned

- The Customer is #1
- Quality Service and Improvement Focus
- Be Flexible
  - Can-Do Spirit
  - Problem Solvers
  - Solutioning
- Strategic Planning
  - Setting your Goals and Objectives Annually



Advice

Our Lessons Learned

- On-Ramps/ Contract Vehicles
  - Seaport, Vector/TANG, OASIS, GSA Schedules
- Partners
  - Big, Small, Trusted, 8a, WO, SDVOSB
- Certifications
  - ISO, DCAA, CMMMMMs
- Know Your Lane
  - Bright Shiny Objects

Keys to Success

- Focus on Growth Two Ways
  1. Financially
     - Diversify
     - Subcontract
     - Prime
  2. Qualitatively
     - Focus on Contracts you Believe “Make a Difference”. Contracts you are proud of and make you feel good when you talk about them
       - » FDA CTP – Insuring tobacco industry compliance with regulations
       - » MWD – Supporting research on Veteran mortality issues
       - » EEO – Insuring an equal opportunity workplace

Questions & Contacts

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Lin Leslie
Business Development Specialist
Lin.Leslie@cesnb.com

www.cesnb.com

U.S. FOOD & DRUG ADMINISTRATION

Closing Remarks

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

U.S. FOOD & DRUG ADMINISTRATION

LUNCH

U.S. FOOD & DRUG ADMINISTRATION

Afternoon Matchmaking Session

Find your Table