Welcome to the Fiscal Year 2023 FDA Virtual Small Business Fair

November 15, 2022

Master of Ceremonies: Kaitlyn Lowe

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

Welcome

Leonard Grant

Director of the Office of Acquisition & Grants Services, FDA

Benjamin Moncarz

Chief Financial Officer, FDA

HCA Welcome

- **The Food and Drug Administration (FDA) recognizes that Small Businesses are the backbone of the US Economy**
  - America's 30 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
- **FDA takes the role of partnering with the Small Business Community seriously**
  - FDA historically meets or exceeds its annual Small Business Goals; FY22 didn't meet our SB goal; Greater effort in FY23.
  - FDA host 2 Small Business Vendor Fairs in FY23
  - 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)**

What FDA's Mission Mean for OAGS

"The Contracts/Grants/IAAs/Purchase Card actions I handle helps…"

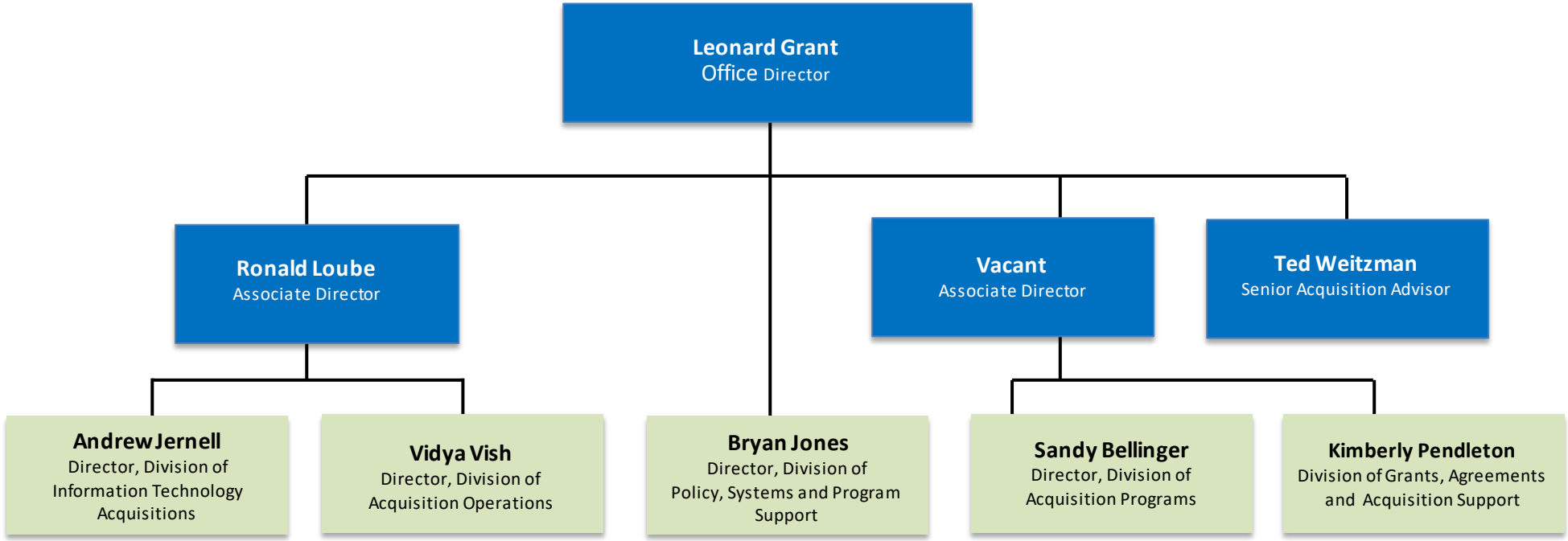
- The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

- 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.

Who We Are



Our staff provides the required depth of knowledge, experience, and workflow support to deliver value across the FDA

FDA Socioeconomic Goals

Small Business Award Categories	FY Goal (FY15-21)	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY 22 Goal (new)	FY22
Small Businesses	38%	50.10%	48.5%	39.64%	36.8%	39.06%	40.09%	34.33%	37.09%	33.49%
Small Disadvantaged Businesses	5.0%	29.50%	27.9%	24.31%	25.0%	27.14%	26.96%	23.84%	25.20%	23.96%
Women-Owned Small Businesses	5.0%	15.90%	17.8%	14.22%	14.1%	14.13%	12.68%	10.33%	11.99%	11.01%
HubZone Businesses	3.0%	2.20%	2.0%	1.40%	1.8%	2.75%	4.09%	3.81%	4.94%	4.48%
Service-Disabled Veteran Owned	3.0%	3.17%	4.9%	3.42%	3.4%	2.81%	3.91%	2.29%	3.80%	3.22%

In 2022, FDA awarded more than $640 Million to Small Businesses!

Commodities and Services Purchased

- ❑ 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.)

Commodities and Services Purchased Continued

- ❑ 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

What does FDA regulate? | FDA

Top 10 Contract Expenditure Categories for FY 2022

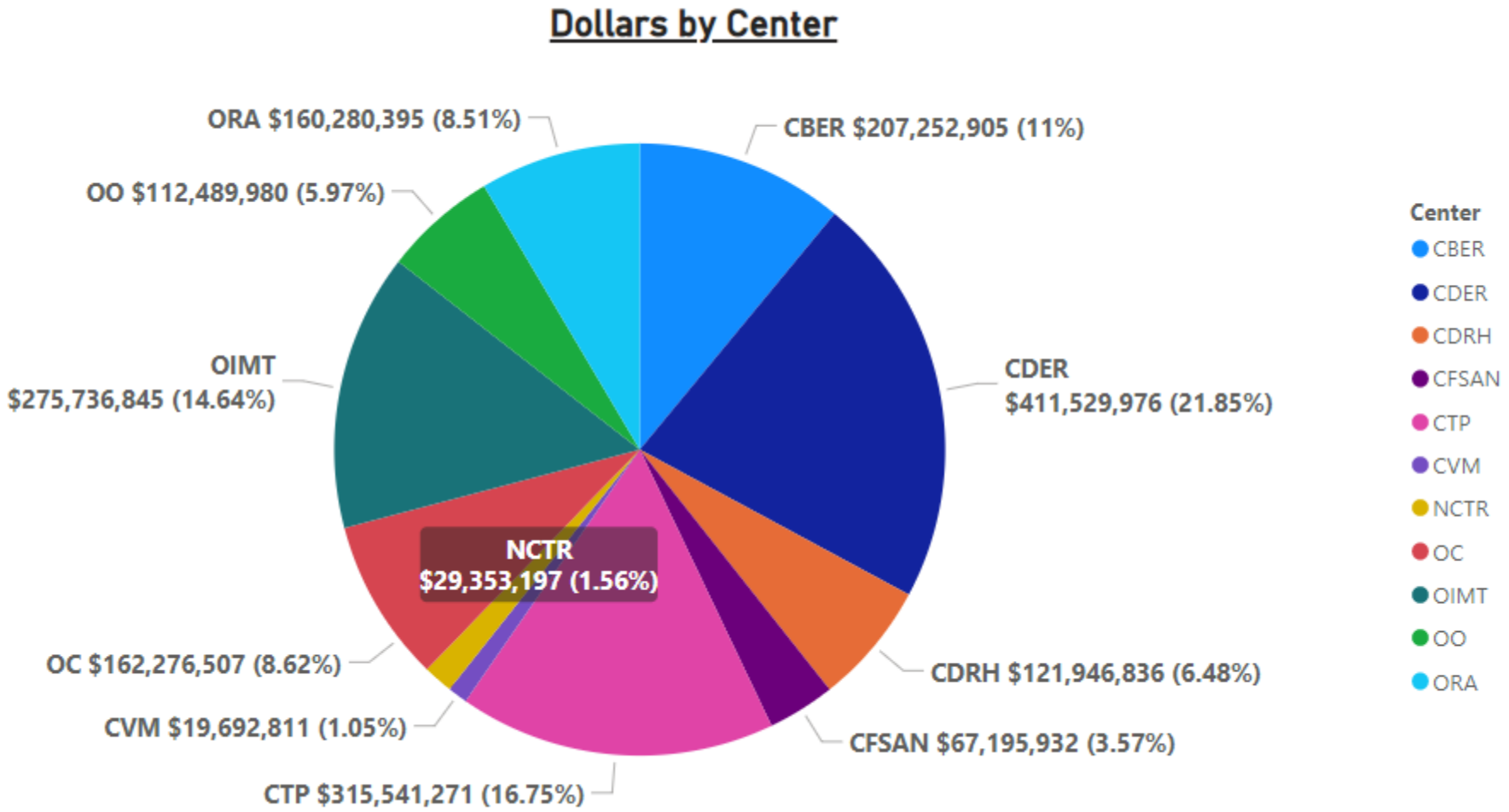
Top 10 Vendors

Vendor Name	Dollars Obligated
TRUE NORTH COMMUNICATIONS INC.	$154,657,000
DELOITTE CONSULTING LLP	$97,989,003
BOOZ ALLEN HAMILTON INC.	$96,646,641
MASSACHUSETTS INSTITUTE OF TECHNOLOGY	$82,182,000
PERSPECTA ENTERPRISE SOLUTIONS LLC	$53,727,010
REI SYSTEMS, INC.	$41,280,352
HARVARD PILGRIM HEALTH CARE INC	$36,661,334
BRILLIENT CORPORATION	$36,227,139
DELOITTE & TOUCHE LLP	$36,221,329
GUIDEHOUSE LLP	$35,498,620
Grand Total	**$ 671,090,427.52**

Top 10 NAICS

NAICS	Dollars Obligated
COMPUTER SYSTEMS DESIGN SERVICES (541512)	$263,578,683
CUSTOM COMPUTER PROGRAMMING SERVICES (541511)	$256,804,721
OTHER COMPUTER RELATED SERVICES (541519)	$229,623,158
ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES (541611)	$227,425,155
ADVERTISING AGENCIES (541810)	$155,294,626
ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES (541990)	$148,886,366
DATA PROCESSING, HOSTING, AND RELATED SERVICES (518210)	$109,249,879
RESEARCH AND DEVELOPMENT IN THE SOCIAL SCIENCES AND HUMANITIES (541720)	$84,756,104
SOFTWARE PUBLISHERS (513210)	$64,880,987
ADMINISTRATION OF PUBLIC HEALTH PROGRAMS (923120)	$63,801,787
Grand Total	**$ 1,604,301,465.82**

Contract Spend by Center/Office



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

OAGS Contact Information

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- **Natasha Boyce, FDA Small Business Specialist, 301-796-3145, natasha.Boyce@hhs.gov**

Opening Remarks

Shannon Jackson

Executive Director, Office of Small and Disadvantaged Business Utilization (OSDBU)

Question and Answer Panel With OAGS Contracting Officers

Panel Introductions

Jennifer Johnson, Contracting Officer, DAP

Ian Weiss, Contracting Officer, DAO

Patricia Natividad, Contracting Officer, DAP

Narissa Charles, Contracting Officer, DITA

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?

Question: What contracting vehicles and approaches are used by the other divisions in OAGS?

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

Question: What is the best way to engage the government if interested in an opportunity?

Question: As a Contracting Officer, can you discuss what you saw from a contractor that was very successful and/or turned around a bad working relationship?

Question: How has the utilization of Best-in-Class, GWACs, and Category Management impacted DITA?

Question: How has the Made-In-America presidential order been carried out at the FDA?

CBER:
Mission and FY23 Priorities

Presenter:
Michael Fischer

CBER Overview – CBER Strategic Plan

Goal 1: Increase nation's preparedness to address threats

Goal 2: Improve global public health through international collaboration

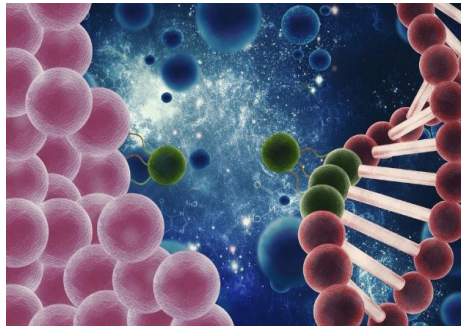
Goal 3: Utilize advances in science and technology to facilitate development of safe and effective biological products

Goal 4: Ensure Safety of biological products

Goal 5: Advance regulatory science & research

Goal 6: Manage for organizational excellence and accountability

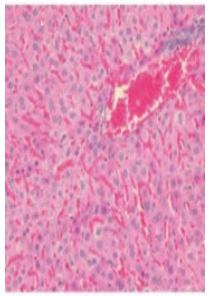
CBER Regulates Complex Products

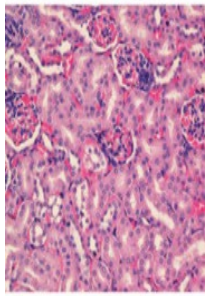


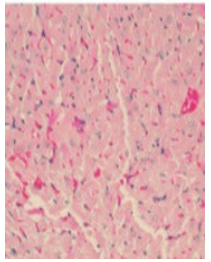
Cell & Gene Therapies

Vaccines: Preventive & Therapeutic

Blood, Blood Components & Derivatives



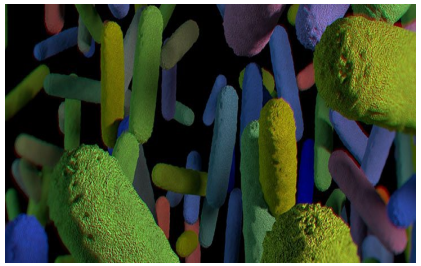




Tissues

Related Devices

Allergenic Products



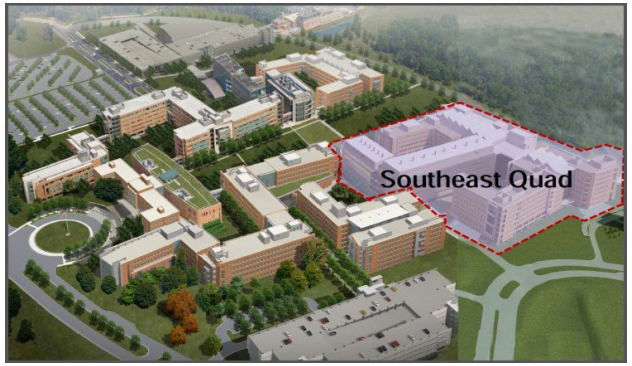
Live Biotherapeutics

CBER Overview – External Services

- CBER Vivarium:
  - Services both CDER and CDRH in providing expert care and support for scientific investments in critical research areas.

- CBER HIVE:
  - The high-performance integrated virtual environment (HIVE). This environment provides high performance computing support to multiple Centers for doing complex data analysis and computations.

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

Future Strategic Objectives

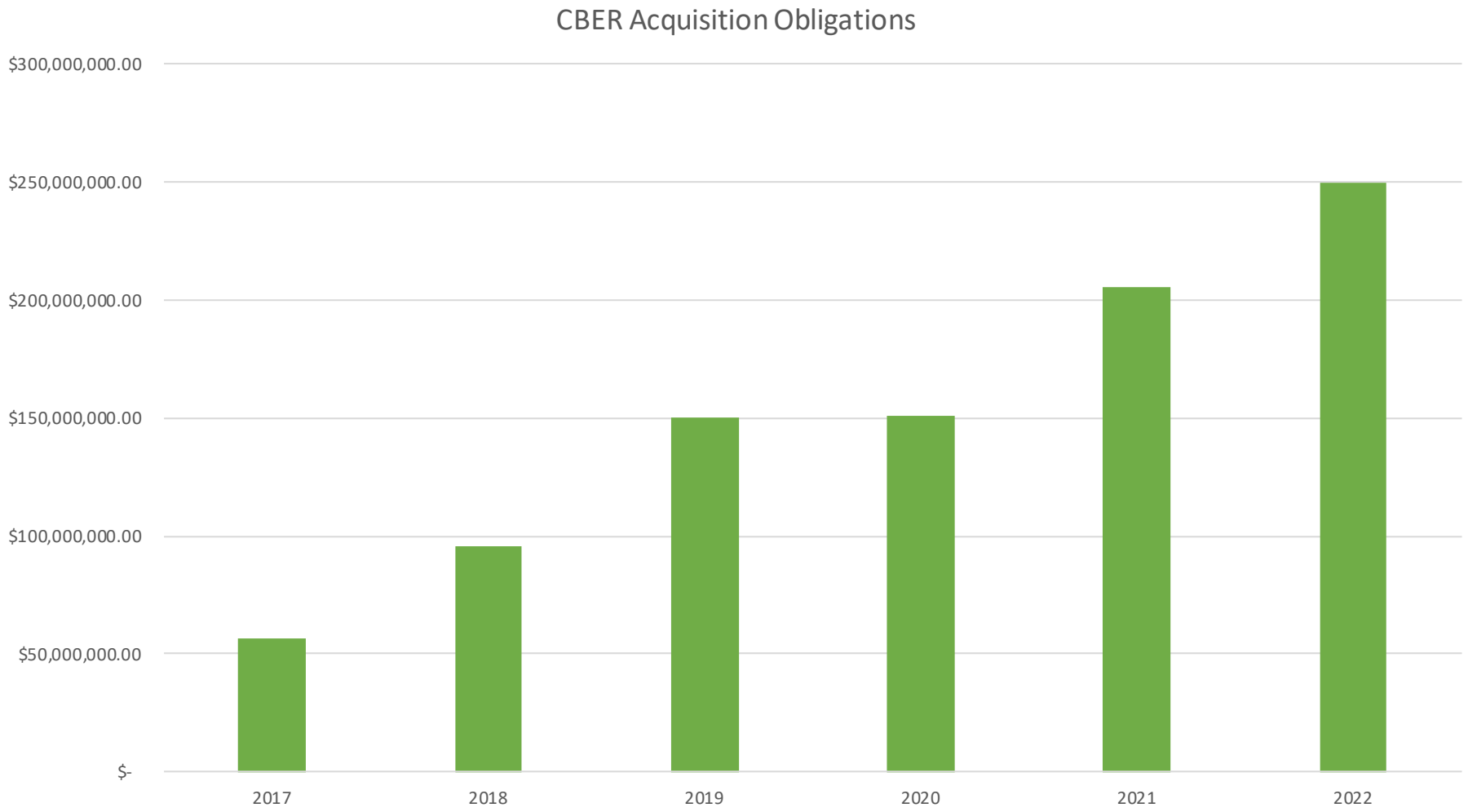
- Scientific Objectives:
  - Meet or exceed user fee action deadlines on submissions and improve performance on tracked meetings
  - Finalize two regenerative medicines and at least three gene therapy guidance documents
  - Continue to focus the CBER research portfolio to address key regulatory issues

- Administrative Objectives:
  - Reduce the FTE vacancy rate
  - Address the need for space allocation for existing and new staff
  - Continue diversity and inclusion efforts to maximize talent, skills and diversity
  - Continue employee engagement activities to increase cohesiveness across the Center
  - Comply with all mandatory training activities

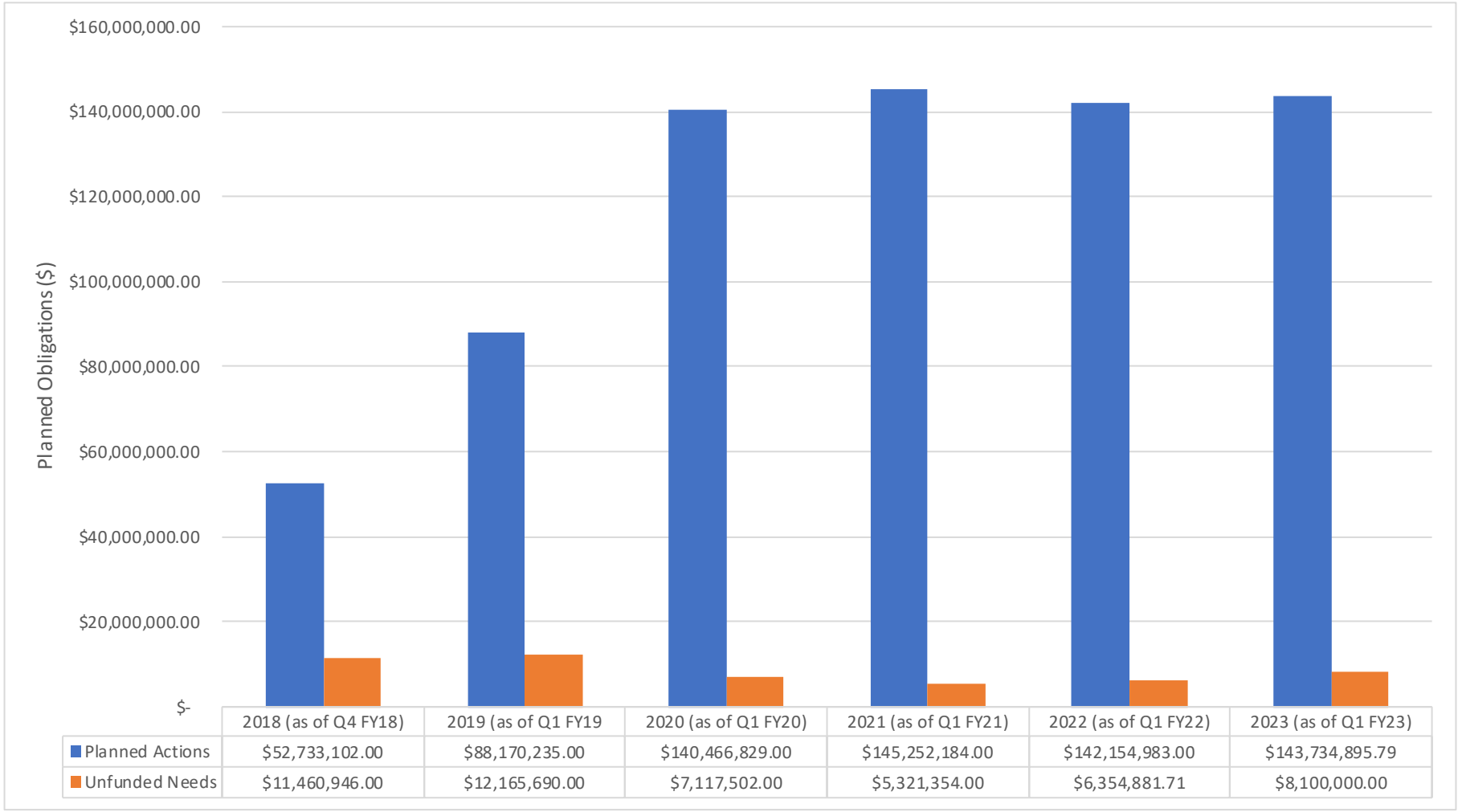
Modernization Efforts

- CBER is embarking on a multi-year effort to modernize regulatory business operations, data management and Information Technology (IT) systems:
  - Goal is to streamline and harmonize operations, improve data quality, and optimize IT systems
  - Project will examine current operations, evaluate needs and align system capabilities to the Center's needs, leveraging advances in technology and best practices
  - Updates about CBER's modernization will be provided and stakeholders input will be solicited through CBER-wide townhall meetings, modernization update emails, and the CBER Modernization SharePoint site.

Acquisition Direction - Workload



Acquisition Direction – Workload Cont.



	2018 (as of Q4 FY18)	2019 (as of Q1 FY19	2020 (as of Q1 FY20)	2021 (as of Q1 FY21)	2022 (as of Q1 FY22)	2023 (as of Q1 FY23)
Planned Actions	$52,733,102.00	$88,170,235.00	$140,466,829.00	$145,252,184.00	$142,154,983.00	$143,734,895.79
Unfunded Needs	$11,460,946.00	$12,165,690.00	$7,117,502.00	$5,321,354.00	$6,354,881.71	$8,100,000.00

Acquisition Direction - Strategic

- The creation and utilization of Category Management/Best-In-Class vehicles
  - Maximizing current resources
  - Leveraging collaborations with other Centers and OC/OO
  - Sponsoring new Agency wide vehicles
  - Last resort: Exploring new indefinite quantity vehicles and agreements for future acquisition growth
- Scientific Support Growth
  - Due to growing workload, scientific support needed to complete scientific objectives
- Increased BAA and Grant Activity
  - To support both COVID and 21st Century Cures Initiatives
- Cost Savings Analysis
  - Implementing strategies aimed at reducing acquisition costs through quantity discounts.

Key Initiatives for FY 2023 and 2024

- Blood Pathogen Reduction:
  - Pathogen reduction technology has the potential to improve blood safety by reducing or eliminating infectious organisms, including bacteria, viruses, and parasites, from blood components intended for transfusion.
  - Mostly R&D related
- Biologic Pharmacovigilance:
  - CBER's role in monitoring various health related data for any biologic adverse effects will remain one of the top priorities for CBER.
  - Key acquisition opportunities will be around access to electronic health records or other health related information
- PDUFA VII Activities
  - As of FY 2023, CBER's anticipated user fee levels under the Prescription Drug User Fee Amendments (PDUFA), will increase over the next 5 years to support CBER's need to increase contract support areas along with increasing FTE levels to support incoming product application submissions.

Possible Small Business Opportunities

General/Science Support Services	• Scientific Support Services (i.e. Lab Technician, Medical Writing Support.) • Sequencing Services • Data Analytic Services
Scientific Equipment	• Mass Spectrometers • Cytometers • Advanced Microscopes • Sample Storage Ultra Low Freezers
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

CDER:
Mission and FY23 Priorities

Presenter:
Beth Goldberg

CDER Mission

To ensure the availability of safe and effective medicines to improve the health of people in the United States.

CDER Regulates

- **Prescription Drugs**

Prescription medicines include any drug product that requires a doctor's authorization to purchase.

- **Generic Drugs**

A generic drug is a drug product that is equivalent to brand name products in terms of quality and performance.

- **Over-the-Counter Drugs**

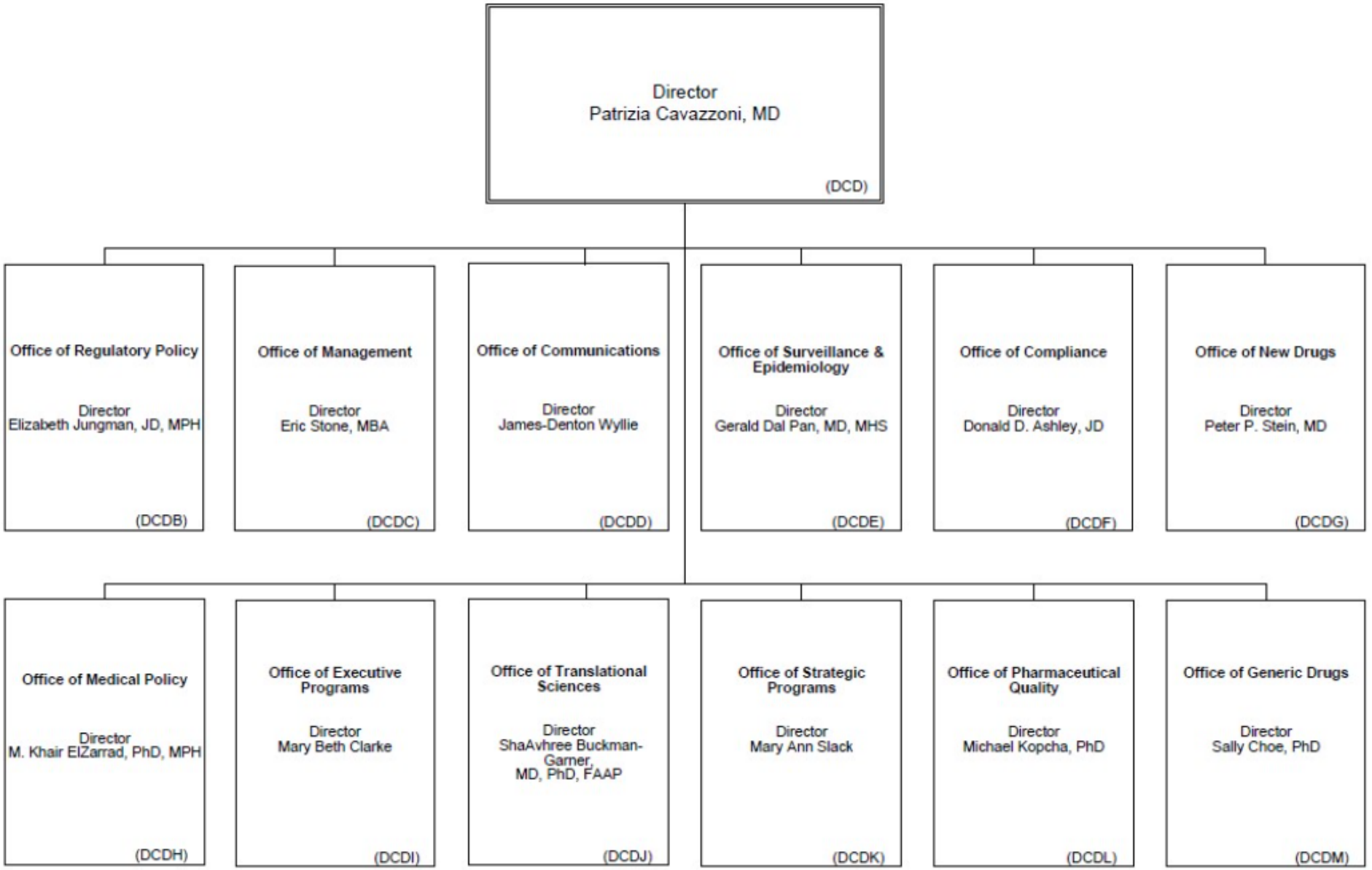
OTC drug products are available to consumers without a doctor's prescription.

Initiatives at CDER

Streamlining the drug development process and ensure drugs are safe and effective

21st Century Review Initiative
Computational Science Center
Critical Path Initiative
Equal Voice Initiative
Modernizing FDA's New Drugs Regulatory Program
Pharmaceutical Quality for the 21st Century
Rare Disease Cures Accelerator
Safety First Initiative
Safe Use Initiative
Scientific Public Private Partnerships and Consortia
Sentinel Initiative
Transparency Initiative
Unapproved Drugs Initiative

CDER Org Chart



CDER Offices

- Office of Communications
- Office of the Center Director
- Office of Compliance
- Office of Executive Programs
- Office of Generic Drugs
- Office of Management
- Office of Medical Policy
- Office of New Drugs
- Office of Pharmaceutical Quality
- Office of Regulatory Policy
- Office of Strategic Programs
- Office of Surveillance and Epidemiology
- Office of Translational Sciences

Where CDER is Located

10001 New Hampshire Ave.
Silver Spring, MD 20903

Types of Requirements

- Lab equipment
- Training
- Research Studies
- Administrative Support
- IT Services
- Professional Services
- Facilities and General Maintenance
- Post-Market Safety/Surveillance

Office of Business Informatics (OBI)

- Creates products to ensure that safe drugs are distributed in the United States
- Serves as a bridge between FDA business units and technology
- Leads the modernization and operation of integrated data management, integrated workflow management, cloud collaboration, capabilities, business intelligence and publishing
- Works on a variety of projects and cutting-edge technologies—Appian, AWS, Cloud, Informatica, Salesforce, and Tableau

Future Potential Small Business Requirements (FY2024)

- **Regulatory Review Systems Production Support** - Business Analysis (BA), Production Support, and Data Quality support for both the existing DARRTS (Document Archiving, Reporting, and Regulatory Tracking System) program and the transition from DARRTS into the CDER Informatics work management capabilities in order to keep CDER IT systems available and functioning for the user community.
- **Communication and Training** - Develop training interventions and strategic communication/outreach programs that prepare and inform CDER employees and stakeholders how to operate the CDER Informatics Platform so stakeholders can use tools and information available to them.
- **CDER Applications Help Desk** - Provide Help Desk services to the users of the CDER IT Apps by providing Tier 0 Help Desk support, customer self-help and FAQs; providing queue management support services for CDER IT Apps; identifying, classifying, and triaging all Help Desk tickets and ensuring proper assignment of tickets; coordinating resolution for high priority tickets; monitoring queues to ensure SLAs targets are met.

CDRH:
Mission and FY23 Priorities

Presenter:
Kyle Roberts

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

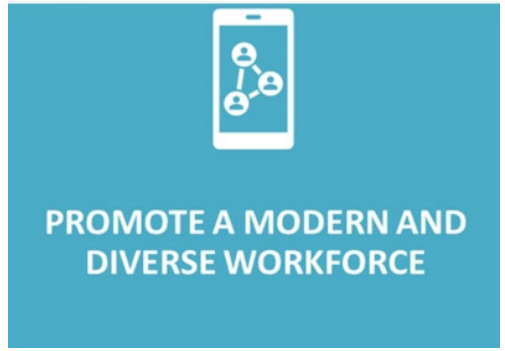
  A modern and diverse workforce prepares us for the future, while maximizing work-life balance and flexibilities, promoting creativity, enhancing diversity, and supporting a culture of trust and empowerment.

- 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.

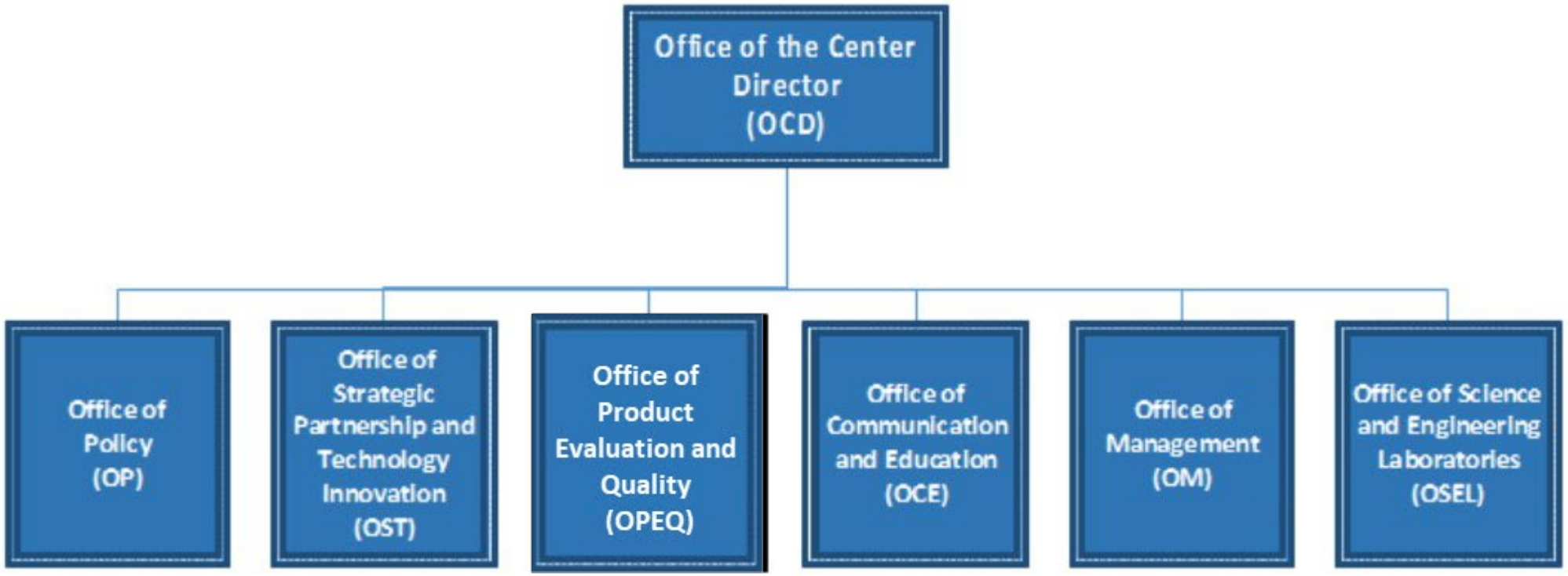


CDRH

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) Office Spotlight

Office of Product Evaluation and Quality (OPEQ)

Assures patients have access to high quality, safe and effective products throughout the total product lifecycle.

Office of Strategic Partnerships and Technology Innovation (OST)

Provides leadership for all scientific collaborative and emerging technology related activities at CDRH.

Center for Devices and Radiological Health (CDRH) FY 23 Opportunities

Medical Device User Fee Amendments 2022 (MDUFA V)

Under the user fee system, medical device companies pay fees to the FDA when they register their establishments and list their devices with the agency, whenever they submit an application or a notification to market a new medical device in the U.S., and for certain other types of submissions.

These fees help the FDA increase the efficiency of regulatory processes and they broaden our expertise with the goal of reducing the time it takes to bring safe and effective medical devices to the U.S. market.

Center for Devices and Radiological Health (CDRH)
FY 23 Opportunities Continued

COVID-19 Supplemental

Projects/Activities	
	-Point of Care/ Over the Counter Devices
	-Post-Market Tracking of Testing and Surveillance Using RWE
	-Pre-Market Review -Surge Capacity & Antigen Testing
	-Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care (SHIELD)

CFSAN:
Mission and FY23 Priorities

Presenter:
LaQuia Geathers

CFSAN's (Center for Food Safety and Nutrition)

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, and
  - 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

Changes in Labels

Side-by-Side Comparison

Original Label

Nutrition Facts
Serving Size 2/3 cup (55g)
Servings Per Container 8

Amount Per Serving	
Calories 230	Calories from Fat 70
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**12%**
Dietary Fiber 4g	**16%**
Sugars 12g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

New Label

Nutrition Facts
8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving	
Calories	**230**
	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

FDA

New Label

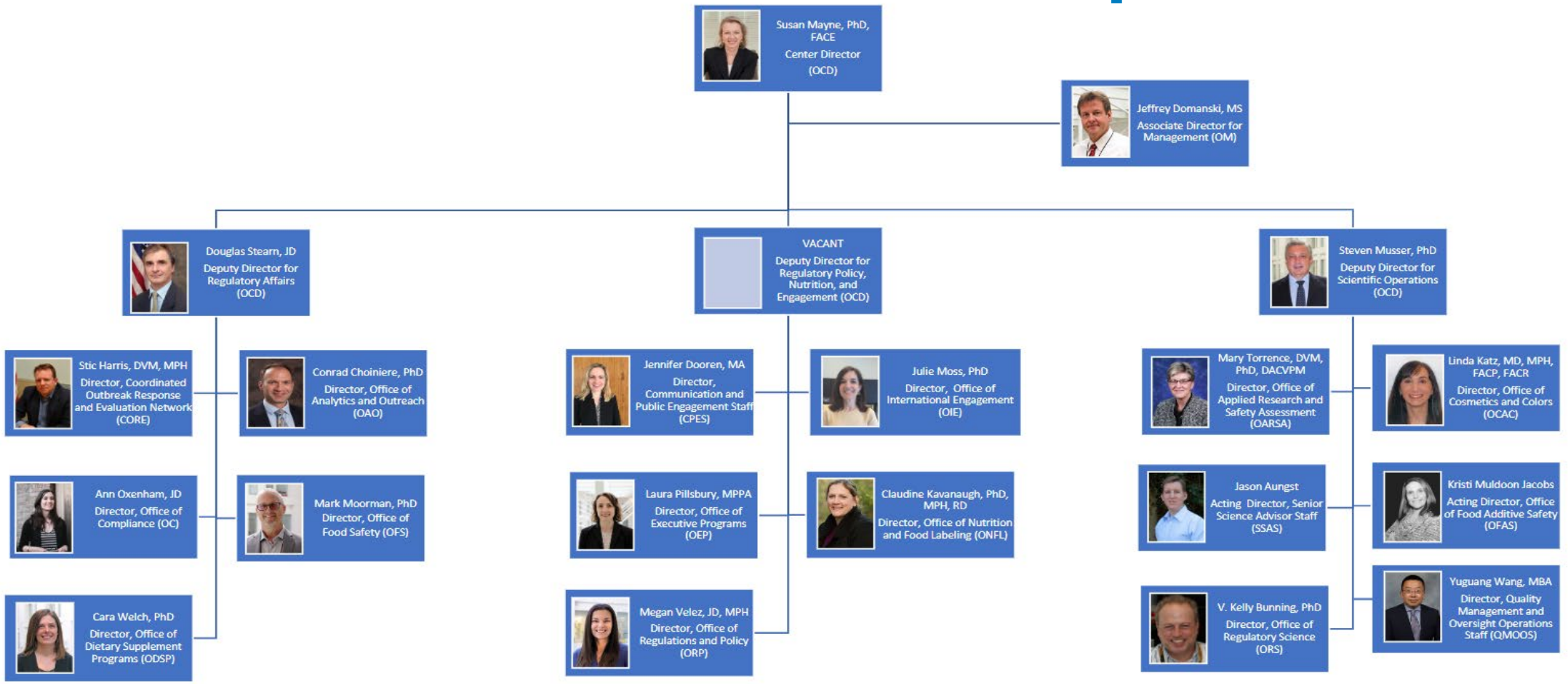
Nutrition Facts
8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving	
Calories	**230**
	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

1. The serving size now appears in larger, bold font and some serving sizes have been updated.
2. Calories are now displayed in larger, bolder font.
3. Daily Values have been updated.
4. Added sugars, vitamin D, and potassium are now listed. Manufacturers must declare the amount in addition to percent Daily Value for vitamins and minerals.

CFSAN's Leadership



CFSAN's 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 (OCAC)
- Office of Dietary Supplement Programs (ODSP)
- Office of Executive Programs (OEP)
- 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)
- Office of International Engagement (OIE)

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

CFSAN's Strategic Initiatives in FY 2023

Emerging Chemical and Toxicology Issues

Closer to Zero: Toxic Elements in Baby Food

New Era

Infant Formula

Improving Healthy Equity Through Nutrition

Sodium

Standards of Identify

Types of Acquisition Services and Supplies

- Scientific Support Services
- Facility Support Services
- 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
- Scientific Equipment and Maintenance
- Office Equipment and Maintenance
- Office Supplies

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

CTP:
Mission and FY23 Priorities

Presenter:
Keith Austin

THE PUBLIC HEALTH REALITY

THE BURDEN OF CIGARETTE SMOKING IN THE U.S.

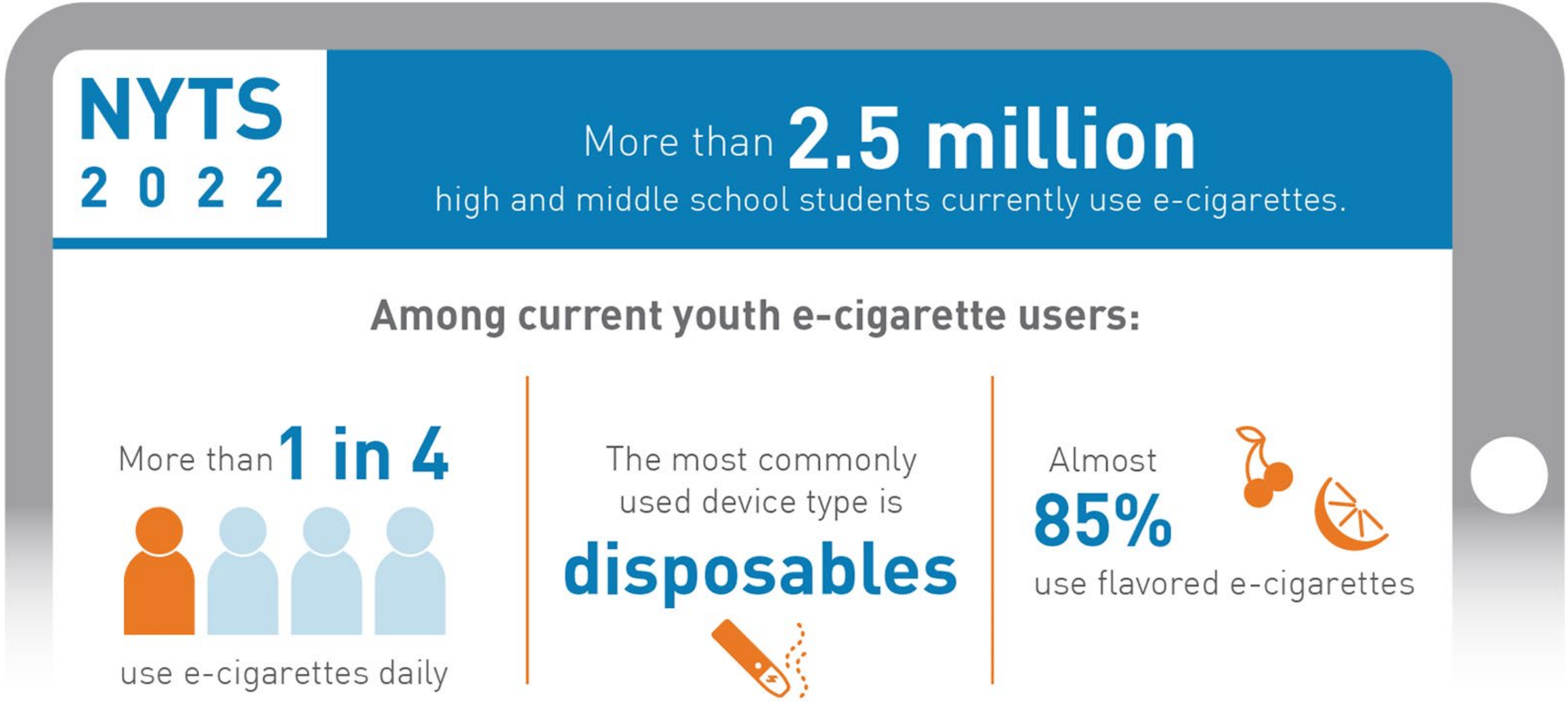
For Adults:

- 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

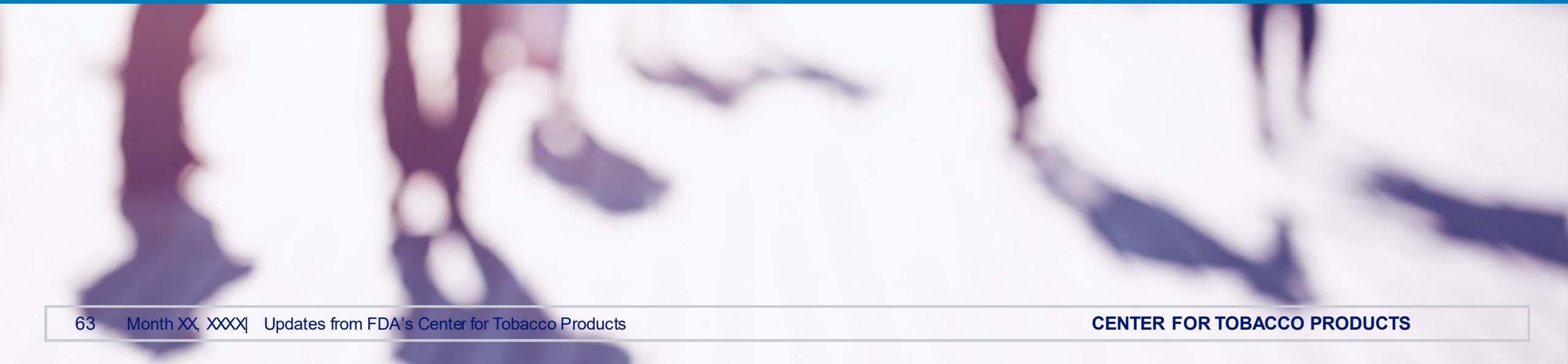
For Teens:

- 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.

FDA'S TOBACCO REGULATORY AUTHORITY

2009: Congress passed the Tobacco Control Act, which gave FDA the authority to regulate the manufacturing, distribution, and marketing of certain tobacco products

2016: Deeming rule extended FDA's authority to more tobacco products, including e-cigarettes that contain nicotine made or derived from tobacco

2022: Congress passed law clarifying FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine

EMPLOYING A 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'S AUTHORITIES

The Tobacco Control Act amended the Food, Drug, and Cosmetic Act to provide FDA authority for:

- Premarket review of new and modified risk tobacco products
- Post-market surveillance
- Product standards
- Testing and reporting of ingredients
- Reporting of harmful and potentially harmful constituents
- Adverse event reporting
- New warning labels
- Advertising and promotion restrictions
- User fees – entirely funded through industry-paid user fees based on market share (not applications)

NOT WITHIN CTP AUTHORITY

In general, CTP's regulatory authorities do not extend to:

- Setting tax rates for tobacco products
- Regulating therapeutic products, such as those marketed to treat tobacco dependence (regulated by other parts of FDA)
- Setting clean indoor air policies
- Regulating tobacco growing
- Requiring the reduction of nicotine yields to zero
- Providing cessation services
- Banning all cigarettes, smokeless tobacco products, little cigars, other cigars, pipe tobacco, or roll-your-own tobacco products
- Changing the minimum age to purchase tobacco products

UNDERSTANDING THE REGULATED PRODUCTS

- **Registration and listing**
  - Companies must register manufacturing facilities and provide a list of all their regulated products.
- **Ingredient reporting**
  - Companies must provide a list of ingredients for regulated products.
- **Submission of health information**
  - All documents related to health, toxicology, behavioral, physiologic effects that are developed after enactment of the statute.
  - Upon request, all documents related to research on health toxicology, behavioral, physiologic, and marketing research.
- **Harmful and potentially harmful constituents (HPHC)**
  - Manufacturers must report levels by brand and sub-brand.
  - Guidance issued defining HPHC as constituents that cause harm or have the potential to cause direct harm (toxicity, addictiveness) or indirect harm (increase initiation or decrease cessation).
  - FDA established a list of 93 HPHC.
  - FDA issued draft guidance on initial reporting of 20 HPHC.

EXPAND SCIENCE BASE FOR REGULATORY ACTION & EVALUATION

FDA also works to expand the scientific foundation for tobacco product regulation:

- Fund research that is then administered by the National Institutes of Health Tobacco Regulatory Science Program
  - Investigator initiated awards
  - Supplements to existing grants or cooperative agreements
  - 14 Tobacco Centers of Regulatory Science (TCORS) in areas of importance to FDA (awarded in September 2013; TCORS 2.0 summer of 2018)
  - Population Assessment of Tobacco and Health (PATH) Study (tobacco longitudinal cohort study)
- Support for national surveys (e.g. NYTS)
- Laboratory analyses (FDA, CDC, NCTR)

FDA'S TOBACCO REGULATORY ACTIVITIES

FDA's Center for Tobacco Products

Review tobacco product applications
to ensure that new tobacco products meet public health standards

Ensure tobacco manufacturers and retailers follow the law through **compliance checks**

Educate
the public, especially youth, about the dangers of using tobacco products

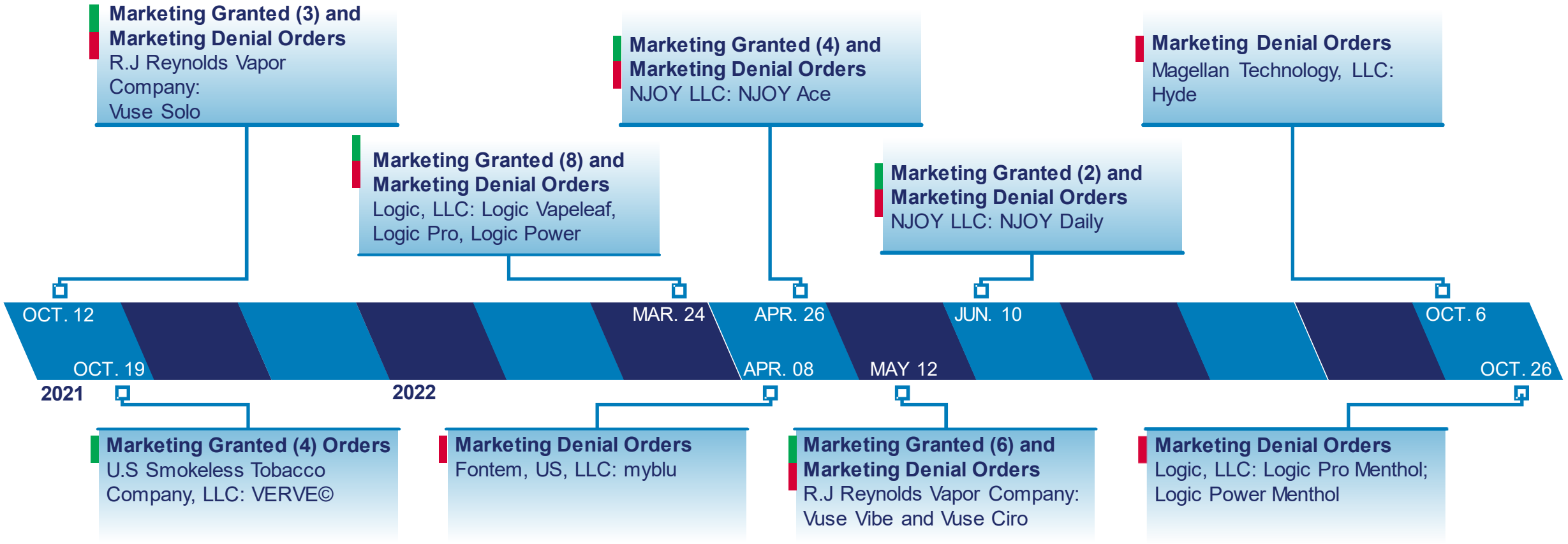
Implement the tobacco control laws through **rules & guidances**

TOBACCO PRODUCT APPLICATION REVIEW

REVIEW NEW PRODUCTS BEFORE THEY CAN BE MARKETED

- The FD&C Act requires that, **before** a *new* tobacco product may be introduced into interstate commerce for commercial distribution in the U.S., the new tobacco product **must undergo premarket review** by FDA and receive marketing authorization through one of the following pathways:
  - **Premarket tobacco product applications** (an application for a new tobacco product that includes comprehensive product information and samples of the product);
  - **Substantial equivalence applications** (an application that compares a new tobacco product to a "predicate" or comparison product);
  - **Exemption requests** (a request submitted for a minor modification to a product involving only a change to an additive)

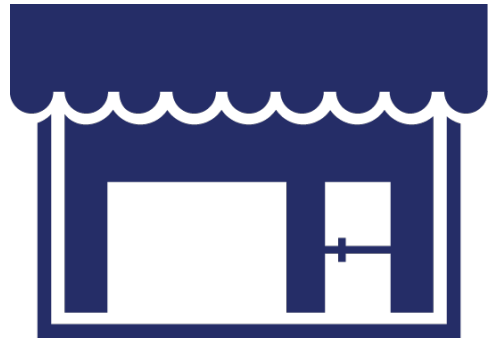
RECENT PREMARKET TOBACCO APPLICATION ACTIONS



COMPLIANCE AND ENFORCEMENT

ENSURE INDUSTRY COMPLIANCE – RETAILERS AND MANUFACTURERS

- **Retailers:**
  - Contracts with states, territories, and tribes to conduct tobacco retailer inspections to ensure compliance with FDA regulations
  - FDA also inspects in jurisdictions without contracts using FDA inspectors



- **Manufacturers:**
  - FDA inspects each registered domestic establishment engaged in the manufacture, preparation, compounding, or processing of tobacco products (biennial)

COMPLIANCE AND ENFORCEMENT ACTIONS (AS OF SEPT. 2022)

Brick and Mortar Retailer Inspections:
OVER 1.3 MILLION

WARNING LETTERS:
OVER 116,000 (OVER 17,000 FOR ENDS)

CIVIL MONEY PENALTIES:
OVER 27,000 (OVER 2,400 FOR ENDS)

NO-TOBACCO-SALE ORDERS:
220

RULES AND GUIDANCES

RULEMAKING PROCESS

Rule/Regulation Proposed

FDA publishes a notice of proposed rulemaking (NPRM) in the *Federal Register* that explains the rule, relies on scientific research, and may ask specific questions

Public Comments Considered

Researchers and the public submit comments to the proposals within the specified time period

FDA is required to solicit, review, and respond to public comments before a proposed regulation can be finalized

Final Rule Issued

After considering comments, FDA may issue a final rule

A final rule is published with the agency's conclusions on comments and thorough explanation of reasons for decisions

PROPOSED MENTHOL & FLAVORED CIGAR PRODUCT STANDARDS (APRIL 2022)

FDA has **proposed product standards** to:

- Prohibit **menthol** as a characterizing flavor in cigarettes
- Prohibit all **characterizing flavors**, except tobacco, in cigars

NICOTINE PRODUCT STANDARD

FDA plans to develop a proposed product standard that would establish a **maximum nicotine level** to reduce the addictiveness of cigarettes and certain other combusted tobacco products

PUBLIC EDUCATION CAMPAIGNS

PUBLIC EDUCATION CAMPAIGNS.

- Rooted in science, FDA's tobacco public education campaigns are critical to our public health mission. FDA focuses on audiences with a higher risk of using tobacco products and uses media campaigns with dynamic advertising to persuade youth to not use tobacco products. To maximize the impact on public health and address the most commonly used product by youth, FDA is prioritizing e-cigarette prevention campaigns for youth.

- FDA has two current public education campaigns:
  - ✓ **The Real Cost**: FDA's award-winning public education campaign, "The Real Cost," continues to prevent youth from tobacco initiation and use.
  - ✓ **Next Legends**: A new tobacco prevention campaign geared toward American Indian and Alaska Native (AI/AN) youth, ages 12–17.

"THE REAL COST" YOUTH E-CIGARETTE USE PREVENTION CAMPAIGN

- "The Real Cost" Youth E-Cigarette Prevention Campaign is **targeted to youth aged 12-17** who have used e-cigarettes or are open to trying them; launched September 2018
- Campaign messages focus on educating youth that using e-cigarettes, just like cigarettes, **puts them at risk for addiction and other health consequences**
- Ads are running on television and online; include location-targeted advertising around high schools nationwide, as well as posters in school bathrooms

NEWEST CAMPAIGN: "NEXT LEGENDS"

FDA recently launched *Next Legends*, a historic tobacco prevention campaign designed to reach American Indian and Alaska Native (AI/AN) youth, ages 12-17, who are at-risk for using e-cigarettes and other Electronic Nicotine Delivery Systems (ENDS).

- There are roughly 400K Native teens in the U.S., and more than half are at-risk for tobacco use, including ENDS.
- AI/AN youth demonstrate higher tobacco susceptibility and tobacco use than their non-AI/AN peers.
- AI/AN youth also have a tendency toward earlier initiation than their non-AI/AN peers.
- These factors ultimately result in disproportionate health outcomes.

There is a strong need for ENDS prevention messaging tailored for AI/AN youth.

CTP'S SMALL BUSINESS INITIATIVE

SUPPORT THE SMALL BUSINESS PROGRAM GOALS

Small Business Outreach

1:1 Small Business Briefing Sessions

Internal Training Presentations/Newsletter

Small Business Database

CTP Small Business Initiative Team

SMALL BUSINESS OUTREACH

- Collaborate with the FDAs Small Business Specialist (OAGS) periodically on developing strategies to foster and support the Small Business Program.

- Attend both internal and external FDA sponsored Small Business Meetings, Small Business Outreach Fairs and Conferences in conjunction with the Small Business Specialist periodically throughout the year.

1:1 SMALL BUSINESS BRIEFING SESSIONS

- Conduct periodic in person 1:1 briefing sessions with Small Businesses at CTP, in conjunction with the FDA assigned Small Business Specialist.

- Briefing sessions are held will small businesses in each of the socioeconomic programs (Small Businesses, Small Disadvantaged Businesses, SDVOB, Women-owned Small Businesses, and Hub Zone Businesses) and 8(a)s allowing them the opportunity to present their capabilities and relevant experiences.

1:1 SMALL BUSINESS BRIEFING SESSIONS, CONT'D

Benefits:

- CTP's ability to present a brief summary/overview of potential "real" fiscal year requirements.
- Small Business' ability to present their capabilities/relevant experiences based on the same or similar requirements.
- Q&A session allowing both CTP and the Small Businesses to get questions answered on the spot as it relates to CTPs requirement; and the small businesses capabilities and relevant experience.
- Assists with CTPs required Acquisition Strategy, Acquisition Planning, and Market Research goals.

INTERNAL TRAINING PRESENTATIONS AND NEWSLETTER TO THE CORS AND PM STAFF

- Conduct internal CTP-Wide presentations through the Acquisition Assistance Team's (AAT) "Ask the Experts" forum to inform and educate CORs, Program Managers, and Subject Matter Experts, etc. on the Small Business Programs, throughout the year.

- Publish articles in our COR Newsletter on various informative topics.

SMALL BUSINESS DATABASE

Created and maintain a CTP Small Business database search tool that lists Small Businesses, to include their pertinent company data, within each of the socioeconomic programs to share with CTP CORs/PMs/SMEs for these purposes:

- Acquisition Strategy
- Acquisition Planning
- Market Research
- Fact Finding and Information Gathering

CTP SMALL BUSINESS INITIATIVE TEAM

- Conduct AAT Small Business Initiative Group monthly meeting to organize, coordinate, and accomplish each of the mission goals.

- Team Members/Supporters:
  - Patricia Pemberton, AAT Director and Small Business Coordinator
  - George Gonzalez, AAT Deputy Director
  - Jill Staton, Team Member/Newsletter Writer/Editor
  - Michelle Creenan, Team Lead
  - Noah Pomato, Team Lead
  - Keith Austin, Team Lead

QUESTIONS?

Call Us (877) CTP-1373

Email Us AskCTP@fda.hhs.gov

Follow Us @FDATobacco

CVM:
Mission and FY23 Priorities

Presenter:
Michelle Fuller

CVM Vision and Mission

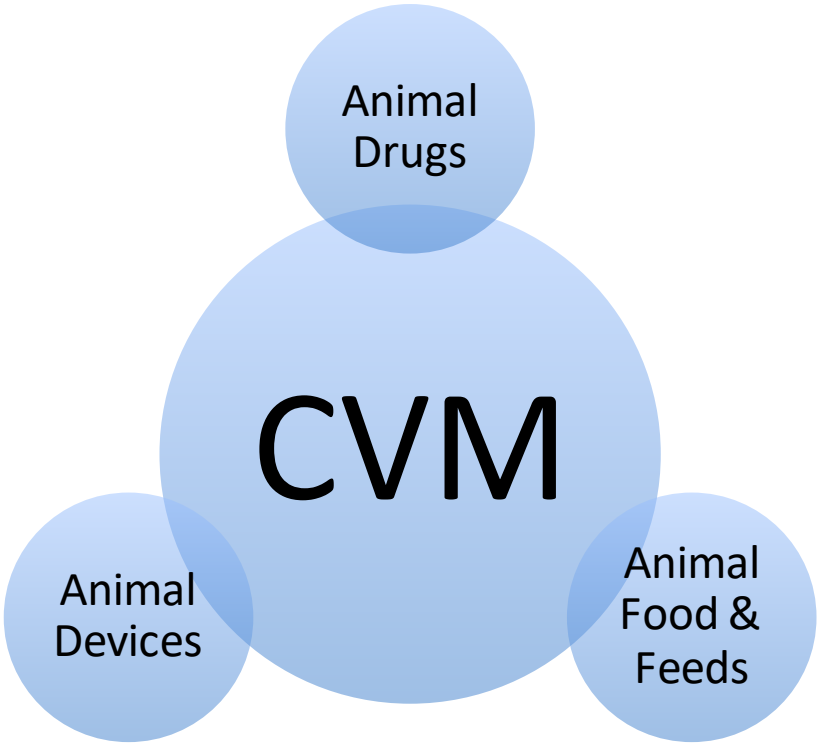
Vision

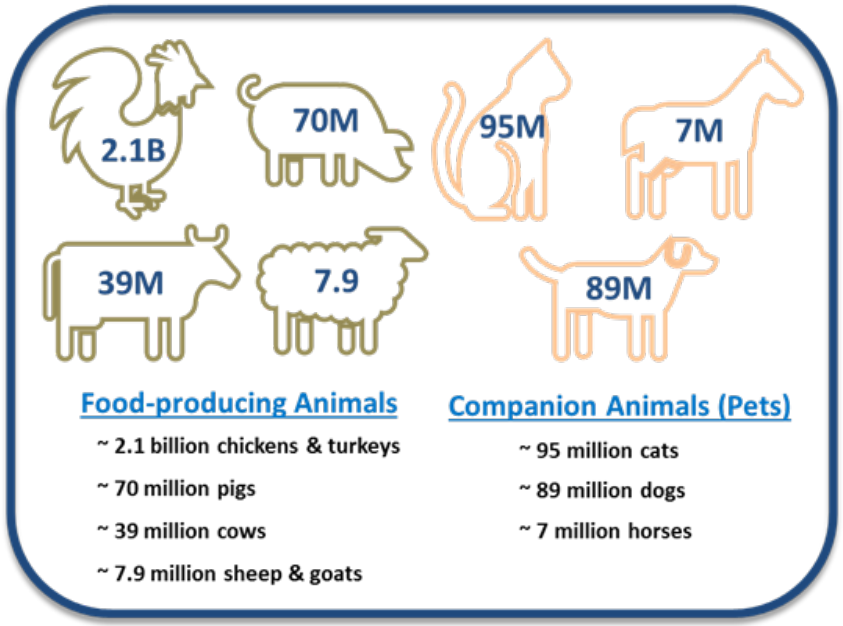
"Excellence, Innovation, Leadership"

Mission

"Protecting Human and Animal Health"

What CVM Regulates

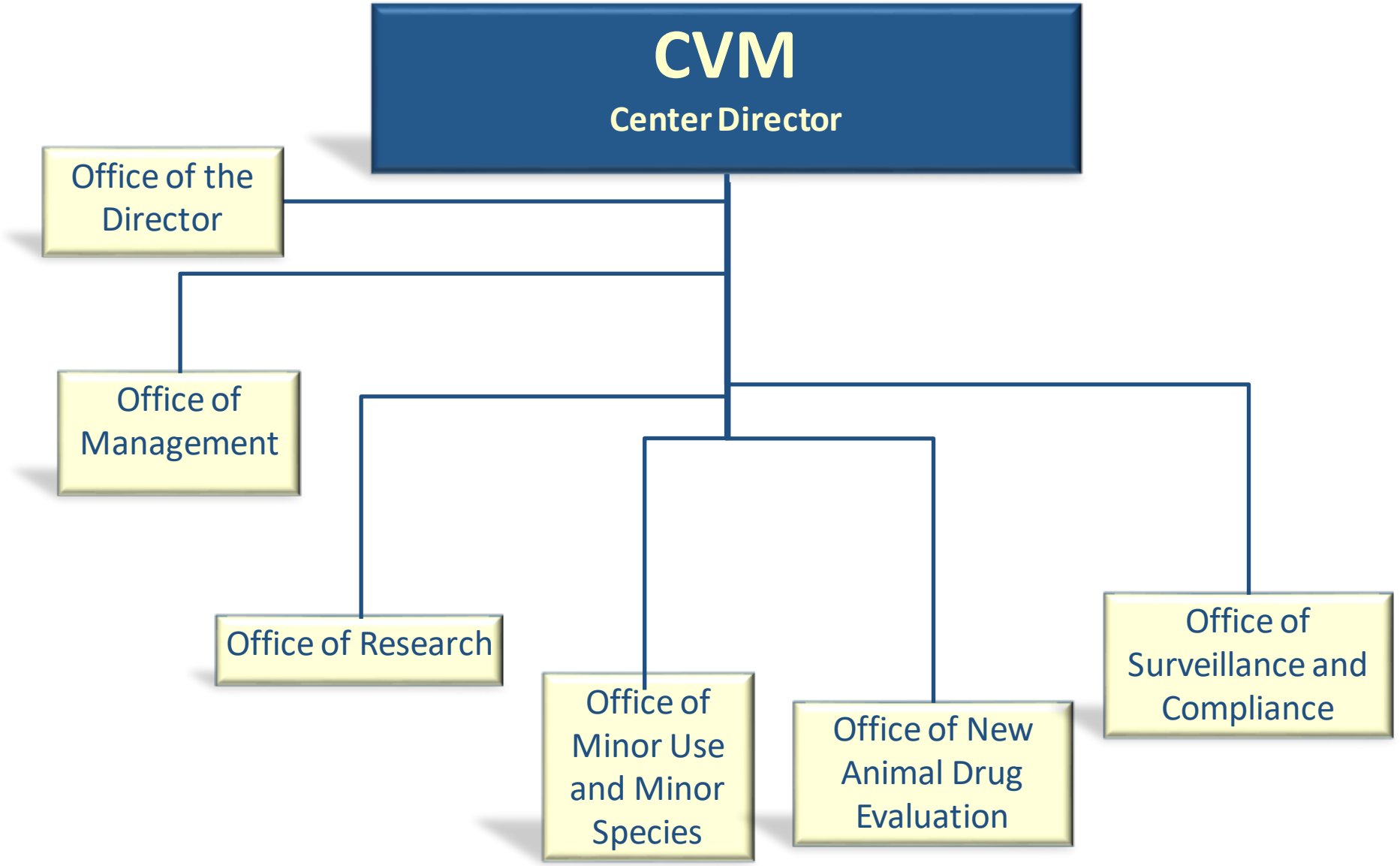




Key Initiatives

- Pre-market Animal Drug Review
- Food Safety Modernization Act (FSMA) Implementation and Food Safety
- Antimicrobial Resistance
- Emerging Technologies and Innovation
- Compounded Animal Drugs
- Post-market Drug Safety, Effectiveness, and Quality
- Outreach to Consumers and Stakeholders

CVM Organizational Chart



Where CVM is Located

- Metro Park North – Rockville, MD
  - Delivery location for most IT and Admin Services

- Muirkirk Road Campus – Laurel, MD
  - Delivery location for lab supplies, lab equipment, and equipment repair

Potential Contract Opportunities FY23

Supplies/Equipment:

- **CVM-CA-23-C-1111** - Purchase of 3 'scientific' Linux based computer towers
- **CVM-OR-23-C-1026** - Contract for purchase of specific VITEK ID Cards
- **CVM-OR-23-C-1126** - Contract for acquisition of reagents/supplies for PacBio Instrument

Services:

- **CVM-OD-23-C-1025** - New contract for 508 Compliance Remediation Services, Base plus 4
- **CVM-OR-23-C-1289** - Preventative Maintenance Services for 3 Sciex MS/MS Systems
- **CVM-OR-23-C-1152** - New contract for sample collection and testing with outside laboratories to expand sampling area and areas not currently covered.

IT Services:

- **CVM-IT-23-C-1224** - IT DME - NEW CONTRACT- OSC Post Approval Quantity Marketed Data Capture (PAQMDC), Part 2b Design thru Implementation.

FDA – Center for Veterinary Medicine
Protecting both Human and Animal Health

Thank you!

NCTR:
Mission and FY23 Priorities

Presenters:
Beverly McKennon
Melody Smith

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

NCTR MISSION

- NCTR conducts scientific research to generate data for FDA decision-making and the development of innovative health approaches.
- As a national scientific resource, NCTR conducts peer-reviewed research to advance scientific approaches and tools required to support public health and to improve FDA's ability to assess the safety of products it regulates.
- NCTR research supports two FDA Goals:
  - 1) Enhance Oversight of FDA-regulated products
  - 2) Improve and Safeguard Access to FDA-regulated products

ABOUT NCTR

- Four Offices
  - Office of the Center Director
  - Office of Management
  - Office of Research
  - Office of Scientific Coordination
- Six Research Divisions
  - Biochemical Toxicology
  - Microbiology
  - Neurotoxicology
  - Systems Biology
  - Bioinformatics and Biostatistics
  - Genetic and Molecular Toxicology

FY 23 PRIORITIES

- Animal Care
- Pathology
- Consolidation of Service Agreements
- PPE

POTENTIAL OPPORTUNITIES FOR SMALL BUSINESSES

- Animal Care
- Pathology
- Consolidation of Service Agreements
- PPE
- Animal Care and Pathology contracts have historically been small business contracts and account for a significant portion of NCTR's operating budget.

ODT:
Mission and FY23 Priorities

Presenter:
Mahesh Choksi

ODT- Vision and Mission

Mission: To provide high quality, secure, and efficient technology, data, and cybersecurity solutions that enable the FDA to promote and protect the public health.

Vision: Trusted technology and data solutions that empower FDA to re-imagine the possible.

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:

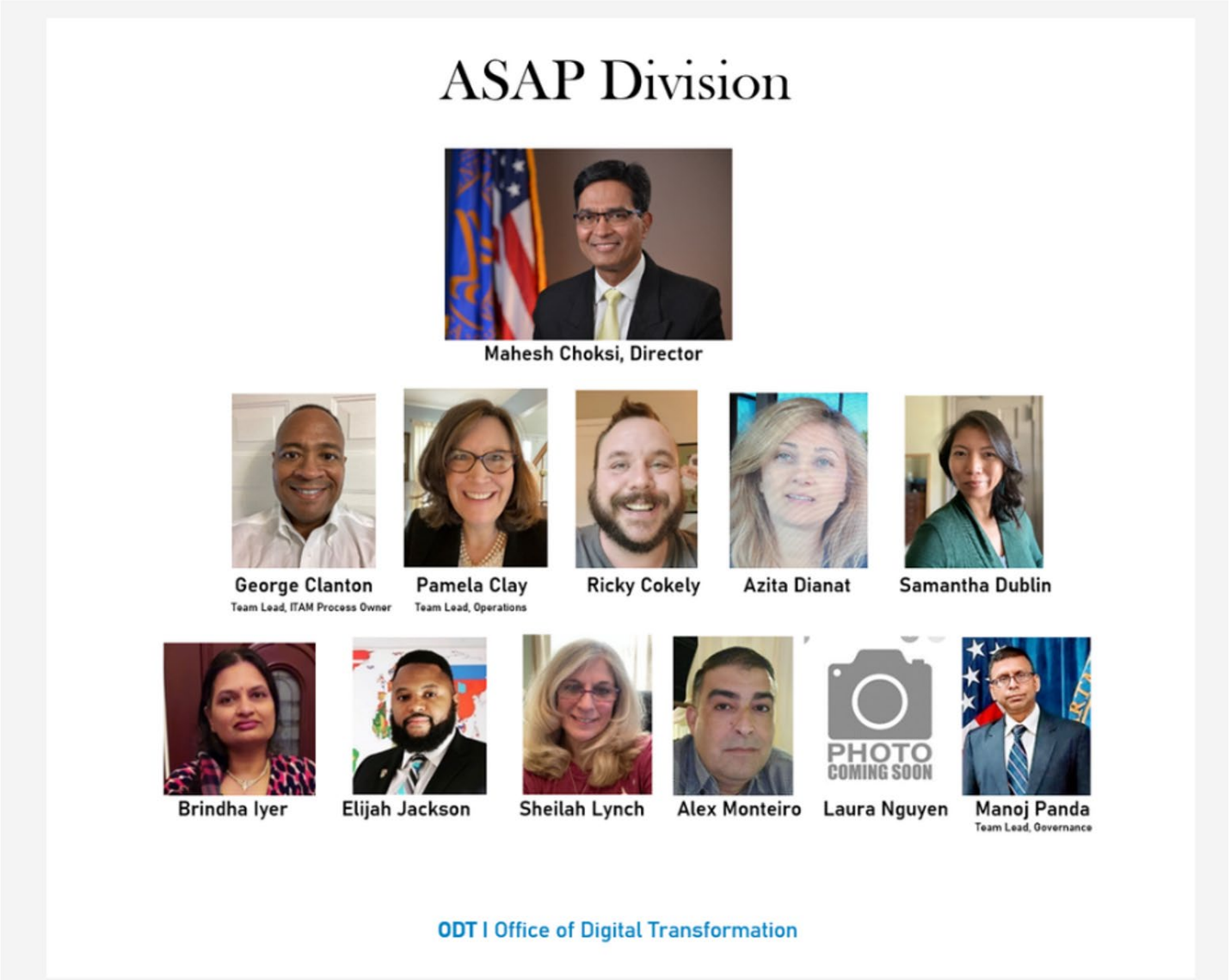
The main goals of the Division are:

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

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

Acquisition Strategies And Partnership (ASAP) Division



ODT FY23 Planned IT Acquisitions

Procurement Title	Total Contract Range
FY23 Distributed Antenna System Modernization (subject to funding approval)	>= $3M and < $7M
FY23 QuickLert Licenses and Maintenance	> $25K and < $250K
FY23 - FY28 Joint Admin Apps Development Environment BPA	>= $20M and < $50M
FY23 Infoblox Hardware Maintenance	> $25K and < $250K
FY23 Atlassian Tools and Maintenance	> $25K and < $250K
FY23 Mailgate Sotware Maintenance	> $25K and < $250K
FY23 ChemBio Office Licenses Renewal	>= $250K and < $700K
FY23 Ivanti Licenses Renewal	> $25K and < $250K
FY23 Portworx Licenses Renewal	> $25K and < $250K
FY23 Neuvector Licenses Renewal	> $25K and < $250K
FY23 AWS Scalr Licenses	> $25K and < $250K
FY23 UPS Modernization	>= $1.5M and < $3M
FY23 Erwin Licenses and Maintenance	> $25K and < $250K
FY23 Enterprise Laboratory Inventory Solution BPA	>= $20M and < $50M

Procurement Title	Total Contract Range
FY23 Bluecoat Software Maintenance	> $25K and < $250K
FY23 Safety Intake Processing Program	>= $7M and < $13M
FY23 Appian Licenses	>= $20M and < $50M
FY23 Enterprise Document Rec Mgmt Platform and Content Services IDIQ	>= $3M and < $7M
FY23 NetOptics Maintenance	> $25K and < $250K
FY23 Netwitness Maintenance	>= $250K and < $700K
FY23 Ping Central Licenses and Maintenance	> $25K and < $250K
FY23 Micromedex Subscription Renewal	> $25K and < $250K
FY23 Personal Data Protection Subscription	> $25K and < $250K
FY23 Printer Logic Printer Installer	> $25K and < $250K

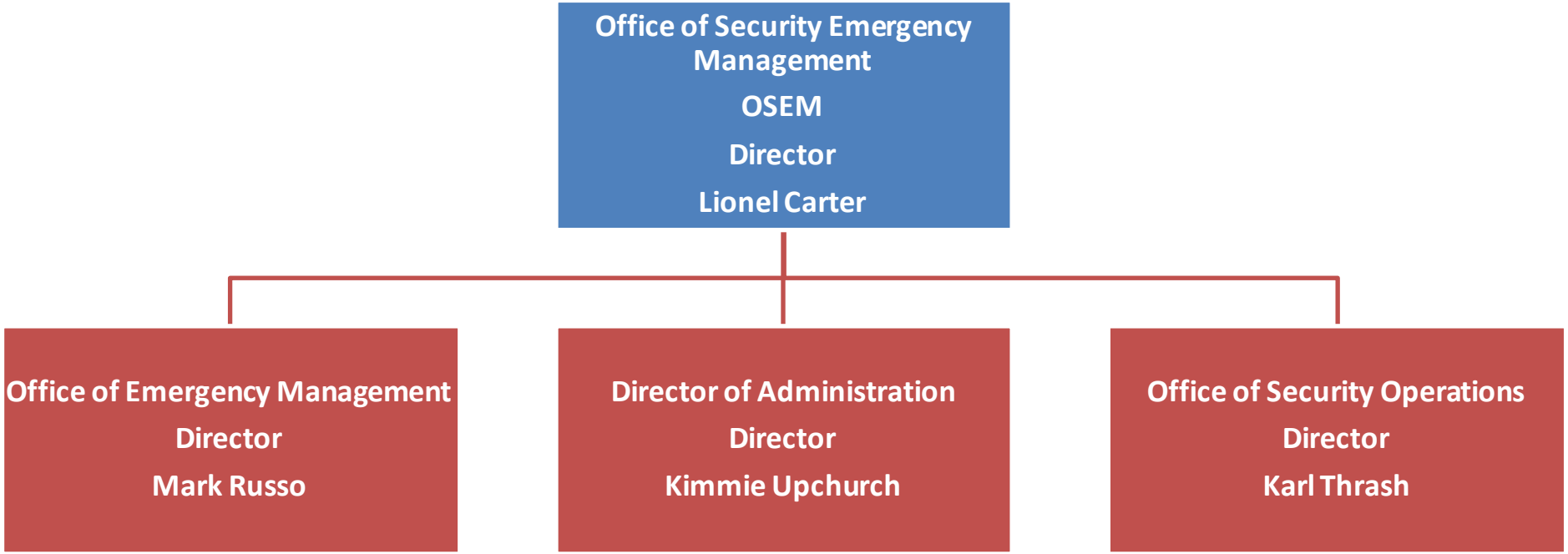
OSEM:
Mission and FY23 Priorities

Presenter:
Jewel Smith

Office of Security and Emergency Management

Our Mission & Leadership Team

OSEM protects FDA's personnel, facilities, and information from threats and ensures that FDA is prepared to manage emergencies and incidents, including those involving FDA-regulated products. OSEM also manages the FDA's Passport/Visa program.



FY23/FY24 Requirements

Active Threat/Critical Response Training	**Provides incident response training to FDA employees.**
Security System IT & Project Management Support	**Stores and maintain security systems on FDA servers and networks.**
Security System Maintenance and Installation	**Provides maintenance and installation to our access controls and video imaging systems along with using various security detection devices.**
HSPD-12 Enrollment & Issuance Stations & Equipment	**Provides equipment used at various locations throughout the agency to enroll applicants into the PIV system and issues/activates PIV cards.**

FY23/FY24 Requirements (Cont.)

Badging Office Administrative Support	Processes FDA personnel through security including fingerprinting, identity proofing, biometric capturing, verifying documentation, and badging issuance.
FDA 24/7 Emergency Call Center	Supports the after-hour Emergency Call Center and provides aid in emergency situations to multiple audiences.
Mission-Critical Subject Matter Expertise & Administrative Support	Provides Subject Matter Experts (SME) that support Personnel Security, Foreign Travel, along with technical services to support the agency's critical security program.
Lock Work Service	Provides Locksmith services for installation, adjustments, repairs, replacement and maintenance of locks throughout the FDA Headquarter facility.
Security Command Center	Provides 24/7 security to FDA's alarm systems nationwide.

FY23/FY24 Upcoming Contract Opportunities

Currently seeking:

- 24/7 Emergency Watch Bill Service to maintain situational awareness, perform after-hours functions during a response.
- Badging Office Administrative Support
- FDA Emergency Operation Center/COOP Site A/V Maintenance
- Passport & Visa/Security Technical Support

ORA:
Mission and FY23 Priorities

Presenter:
Michelle Hawley

ORA MISSION AND VISION

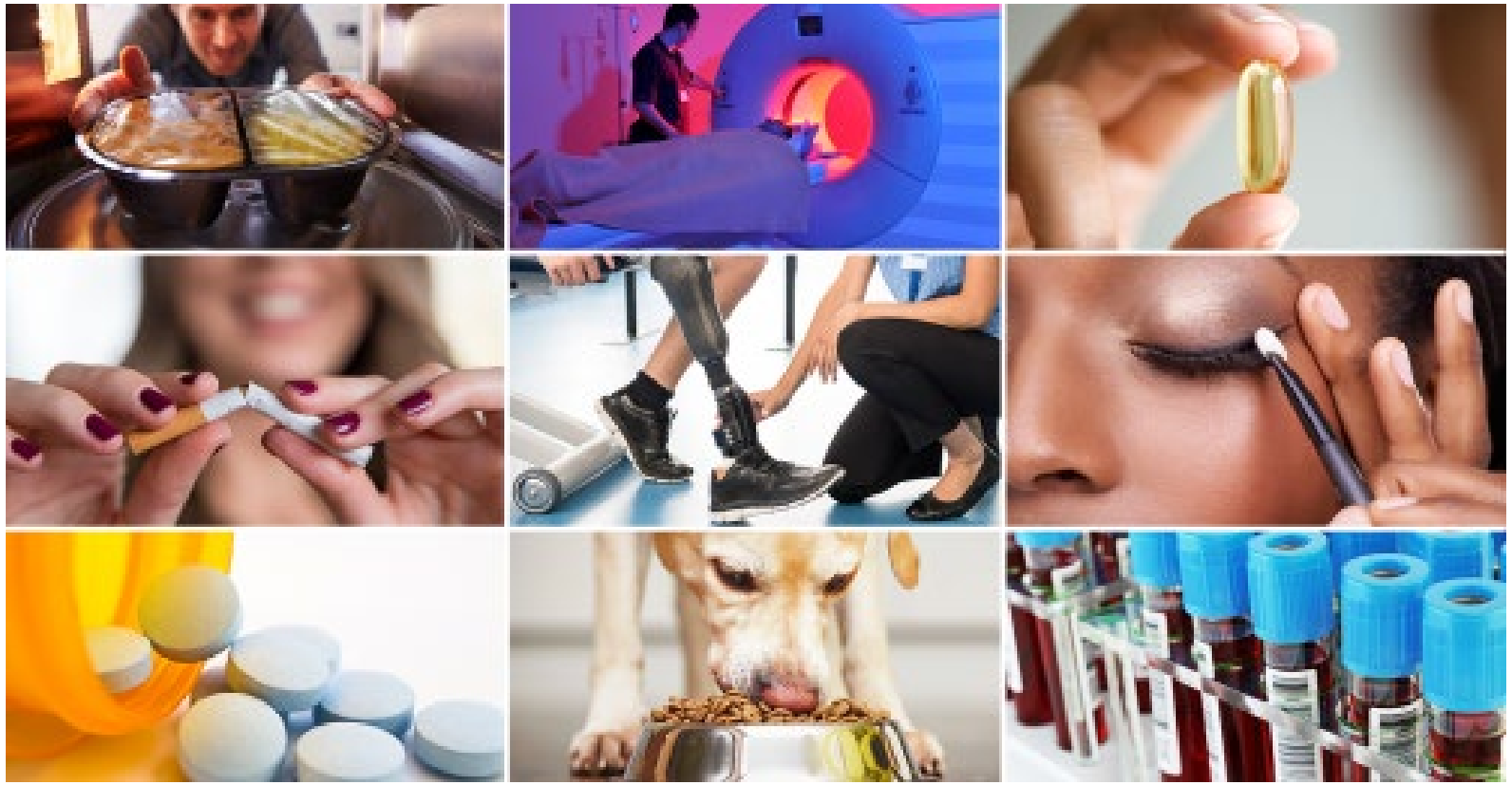
Mission

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

Vision

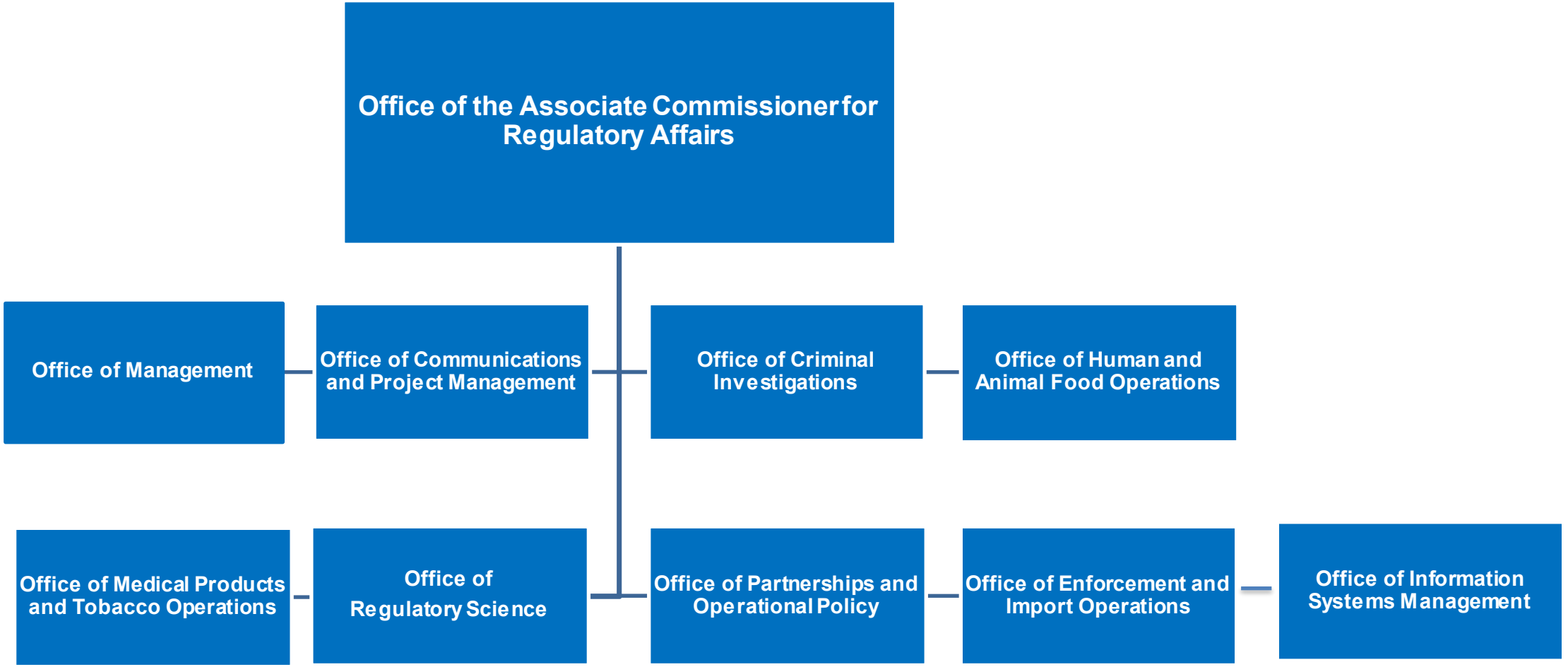
Public health is protected, promoted, and advanced

Office of Regulatory Affairs



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

Office of Regulatory Affairs



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

Office of Regulatory Affairs

ORA conducts inspections in foreign countries and has offices in:

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

Questions?

Thank you!

Small Business Success Story:

Centeva

John Esplin

President

Centeva

Centeva is a management consulting firm offering professional and technical services.

Our professional capabilities:

- Project, Program, and Portfolio Management

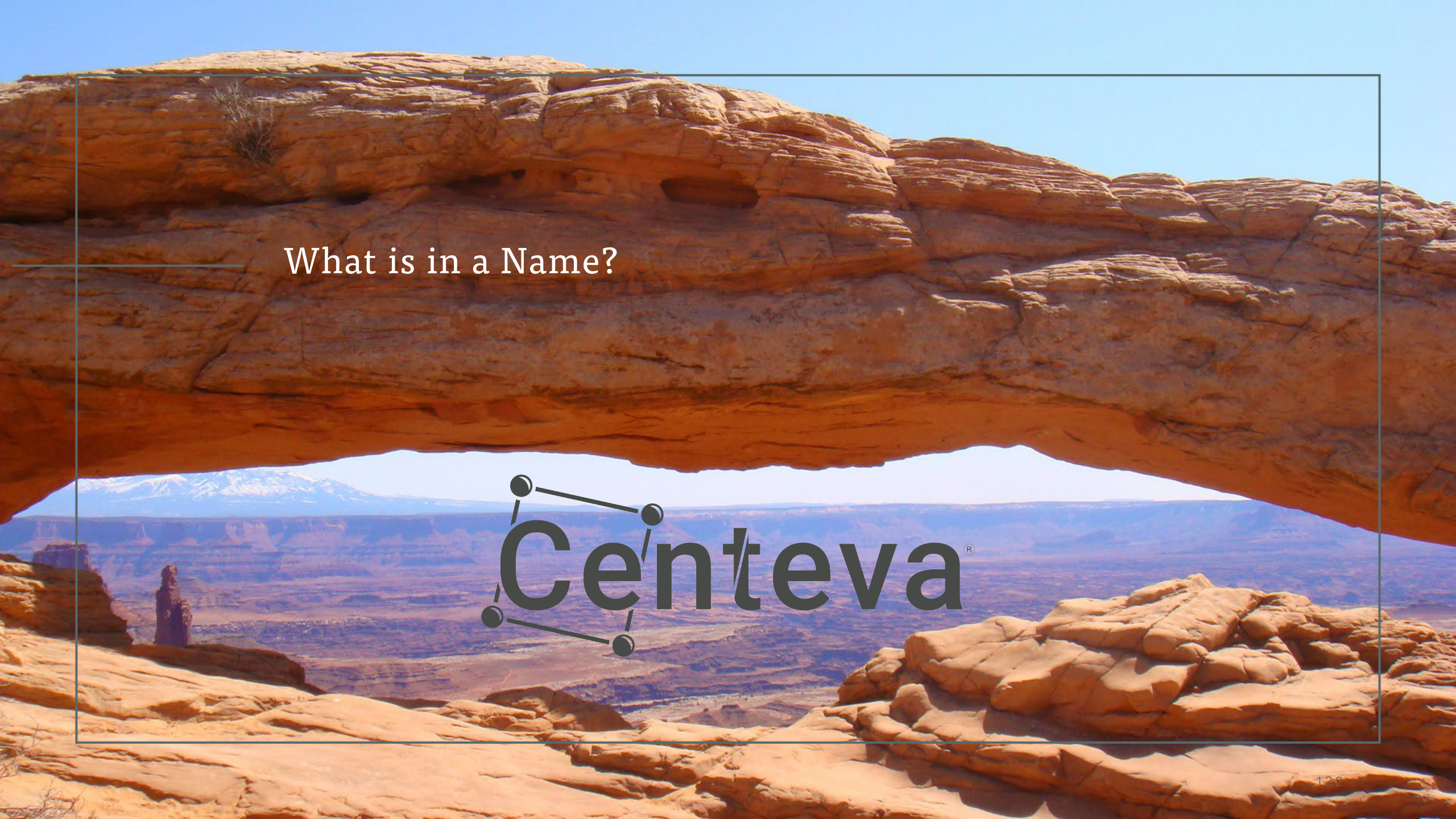
Our technical capabilities:

- Systems, Software, Integration, and Data

Our Domain Expertise include:

- Regulatory Oversight (Licensing, Permitting, Inspections, and Audits)
- Supply Chain (Acquisition Management, Contract Management, and Logistics)

What is in a Name?



Our Start

Failure: Caught up in maximizing short-term profitability while holding a "we know best" attitude, another company failed to deliver the level of service required by one of their Federal customers.

Opportunity: Possessing key domain expertise, Centeva's principals were given an opportunity to step up and fill the void.

Key Takeaway: Centeva would not exist today if that other company had simply listened to their customer and ensured they were delivering in accordance with scope and expectations.

Growth Strategy

Full and Open Competitive Awards

Small Business Prime Awards (Large Sized Efforts)

Large Business Subcontracting (Large Size Efforts)

8(a) and SB MAC (BIC, GWAC, and Agency)

SB Competitive Awards

8(a) Competitive Awards

8(a) Sole Source Awards

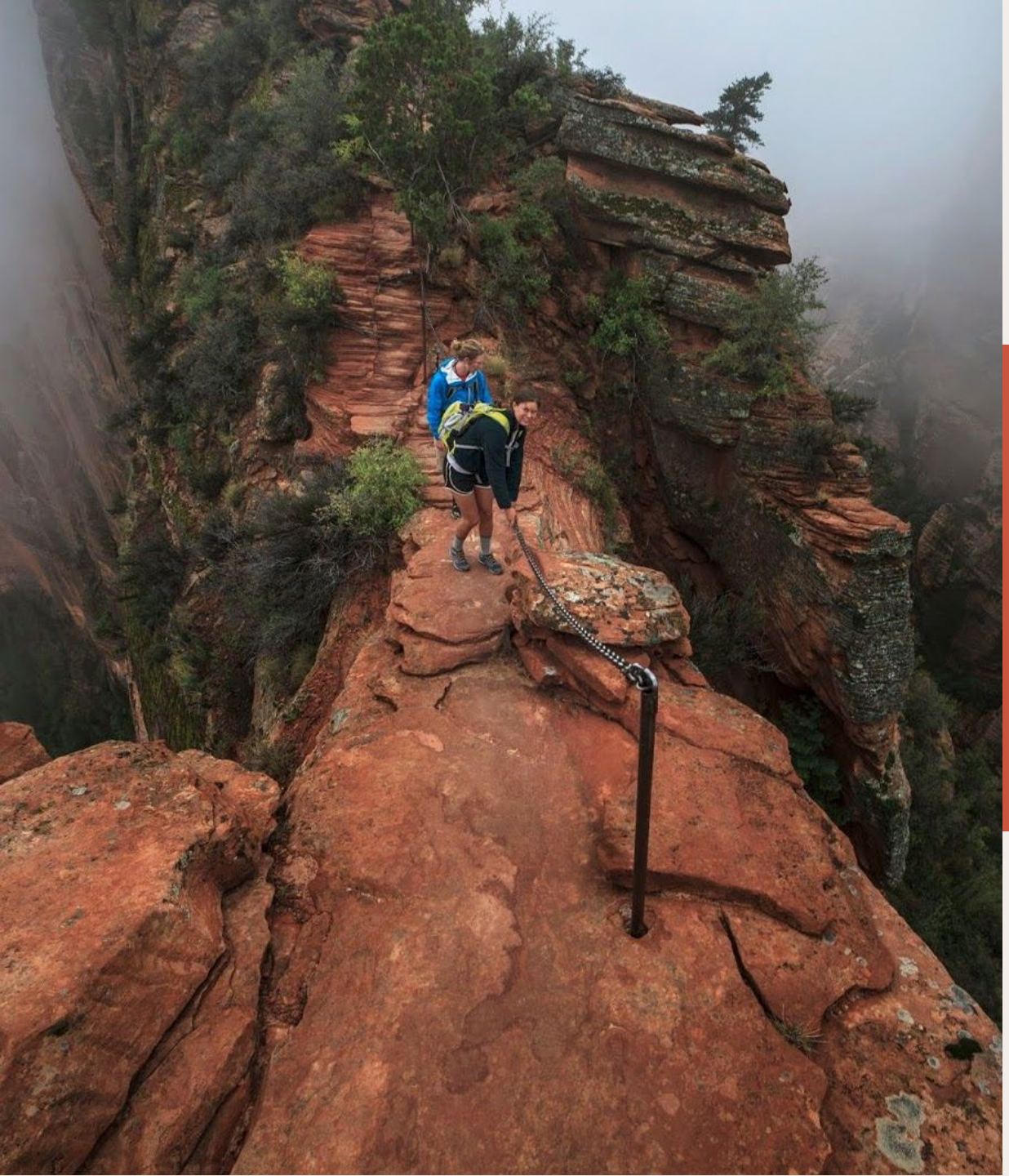
Growth Principles

- ✓ Have a Plan
- ✓ Establish Our Hedgehog
- ✓ Stay the Course
- ✓ Proactively Invest in:
  - ❑ People
  - ❑ Core Capabilities
  - ❑ Domain Expertise

Key Takeaway: When Centeva has struggled, it has often been as a result of our deviation away from these principles.

What has Worked

- Small Business Office Engagement
- Ecosystem of Synergistic Firms
- Pool of Consultants (w/Former Agency Personnel)
- Attending every Engagement Opportunity Possible
- No shortcuts



Call to Action

- Know Your Customer
- Be Flexible and Constantly Listen
- Deliver Strategic Value (Don’t Simply Execute Tasks)
- Stop Taking Shortcuts

Thank You

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Closing Remarks

Bryan Jones

Director, Division of Policy, Systems, and Program Support, FDA

Thank you for joining us!

For Questions and Feedback, please email:

FDA-Small_Business_Outreach@fda.hhs.gov

Matchmaking meetings are very limited and not all small business vendors will be able to sign up for a meeting.
Randomized meetings will be scheduled from 12:30 – 1:30pm