FDA's History: Past, Present and Future

Presented To

University of California, Irvine

Graduate Degree Programs

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March 23, 2018

Acknowledgments

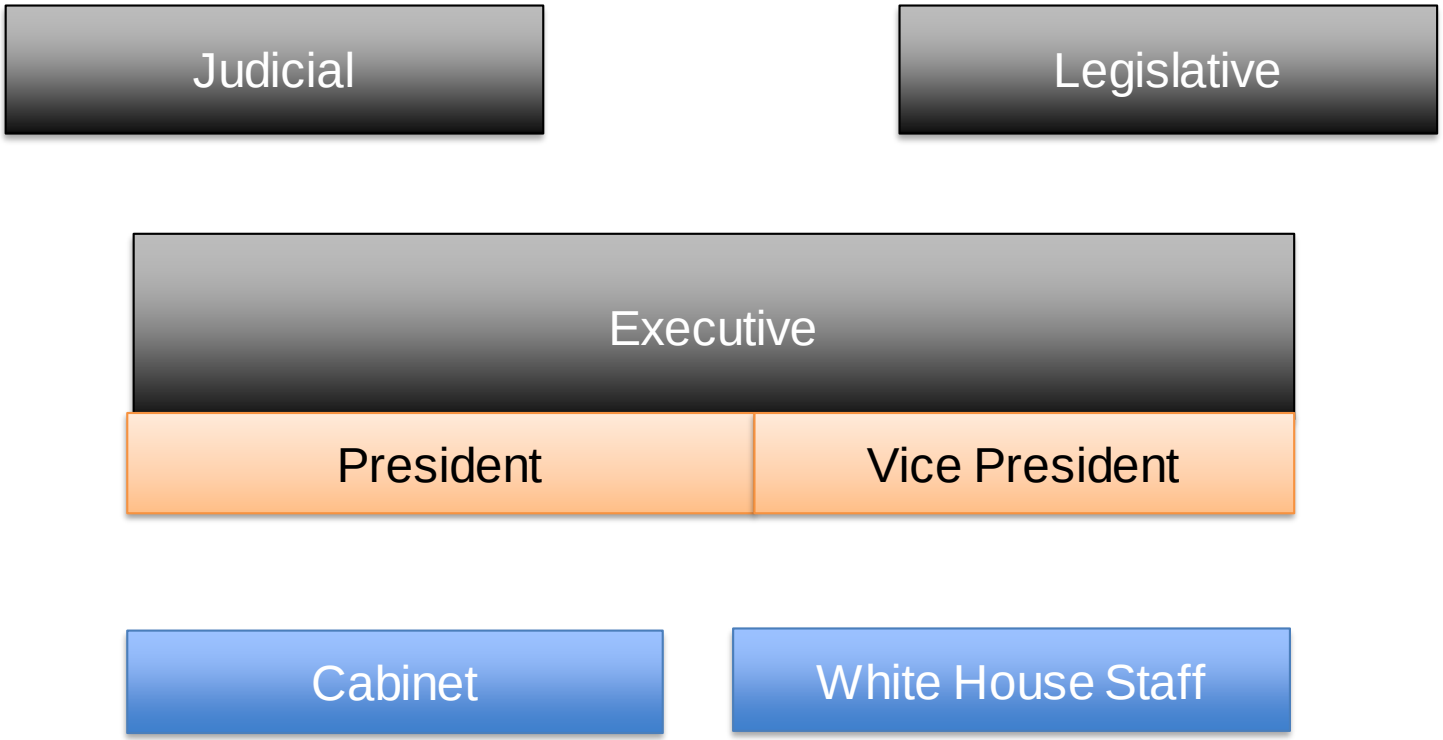
Information contained in these slides are all based on public information.

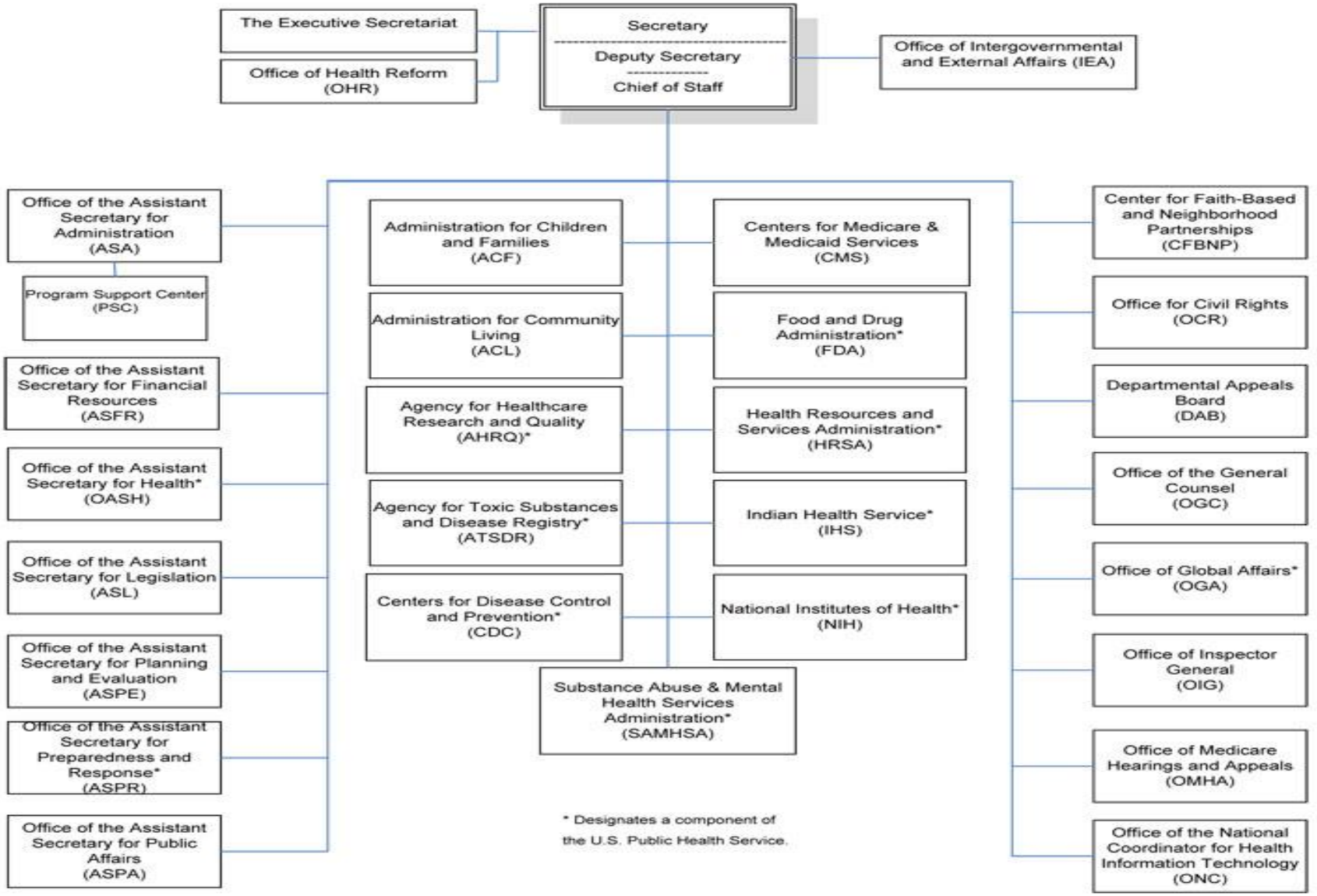
Thanks to:
Dr. William Martin, Director,
Pacific Southwest Food and Feed Laboratory, Office of Regulatory Affairs, FDA, for the designs and material included in History slides

and

Office of Regulatory Affairs for the information provided for Program Alignment slides.

U. S. Government:




The Executive Secretariat
Office of Health Reform (OHR)
Secretary
Deputy Secretary
Chief of Staff
Office of Intergovernmental and External Affairs (IEA)
Office of the Assistant Secretary for Administration (ASA)
Program Support Center (PSC)
Office of the Assistant Secretary for Financial Resources (ASFR)
Office of the Assistant Secretary for Health* (OASH)
Office of the Assistant Secretary for Legislation (ASL)
Office of the Assistant Secretary for Planning and Evaluation (ASPE)
Office of the Assistant Secretary for Preparedness and Response* (ASPR)
Office of the Assistant Secretary for Public Affairs (ASPA)
Administration for Children and Families (ACF)
Administration for Community Living (ACL)
Agency for Healthcare Research and Quality (AHRQ)*
Agency for Toxic Substances and Disease Registry* (ATSDR)
Centers for Disease Control and Prevention* (CDC)
Substance Abuse & Mental Health Services Administration* (SAMHSA)
Centers for Medicare & Medicaid Services (CMS)
Food and Drug Administration* (FDA)
Health Resources and Services Administration* (HRSA)
Indian Health Service* (IHS)
National Institutes of Health* (NIH)
Center for Faith-Based and Neighborhood Partnerships (CFBNP)
Office for Civil Rights (OCR)
Departmental Appeals Board (DAB)
Office of the General Counsel (OGC)
Office of Global Affairs* (OGA)
Office of Inspector General (OIG)
Office of Medicare Hearings and Appeals (OMHA)
Office of the National Coordinator for Health Information Technology (ONC)
* Designates a component of the U.S. Public Health Service.

FDA is responsible for:

- *protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation*
- *regulating tobacco products*

FDA History

Since 1906. . .

The Dining Room of "The Poison Squad"

Our Challenges

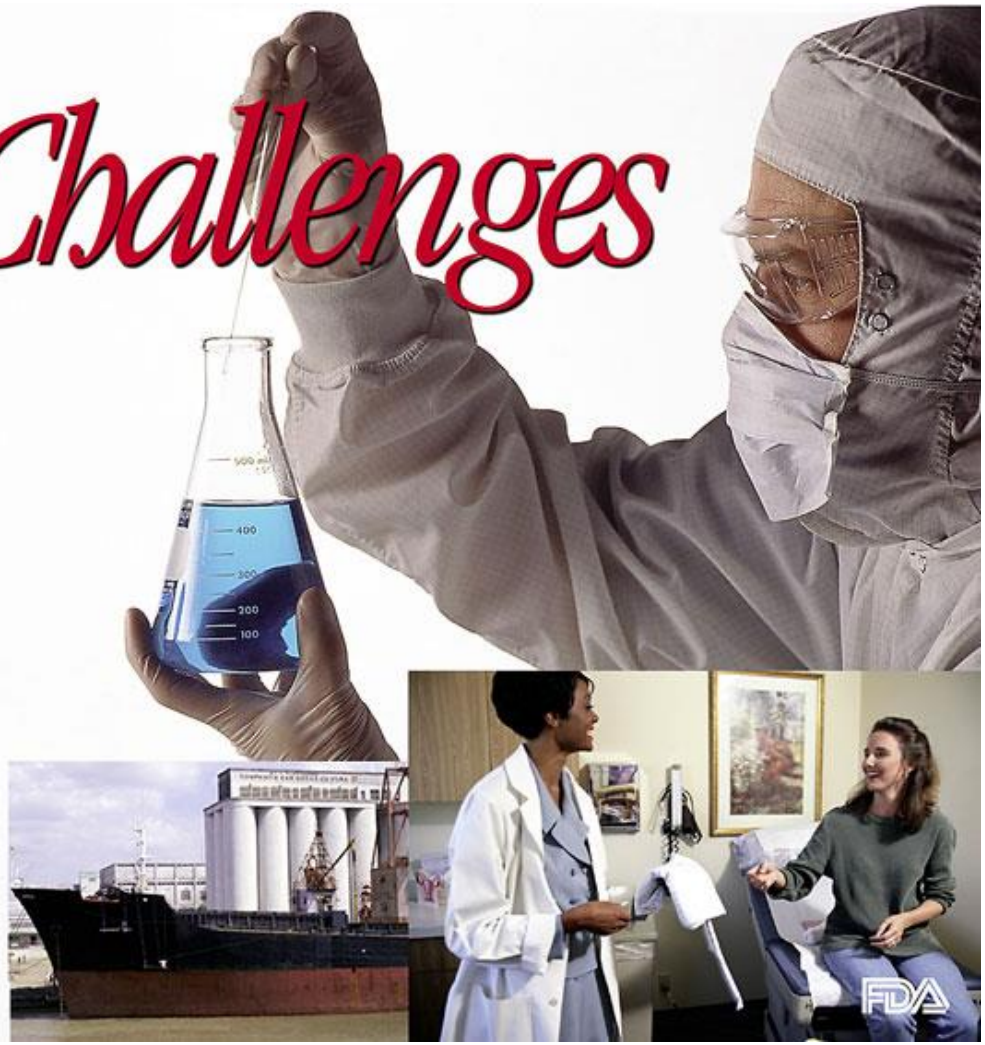
Scientific Breakthroughs

More Sophisticated Products

New Public Health Threats

International Commerce

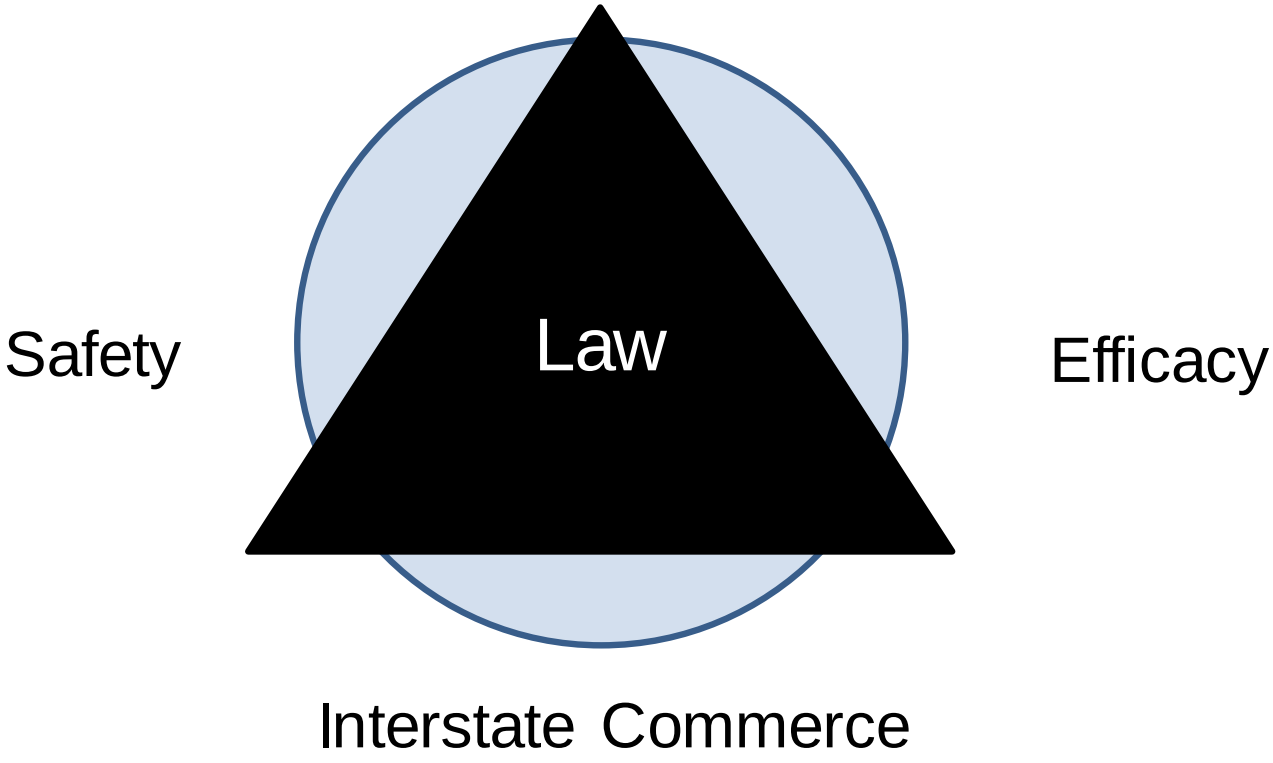
Consumer Information



- *FDA uses regulations and product standards as the "yardsticks" that define specific requirements manufacturers must follow to assure product safety and to provide accurate information to health professionals and consumers.*

- *FDA works with foreign governments to encourage the safety and quality of imported products by making sure that **foreign** standards are equivalent to those enforced by FDA.*

- FDA has ***authority*** over regulated products in *Interstate Commerce:*



Origins

The FDA can trace its history back to the appointment of chemist Lewis Caleb Beck to the Agricultural Division in the Patent Office in 1848.

However, the nauseating condition of the meat-packing industry that Upton Sinclair captured in The Jungle was the final precipitating force behind both a meat inspection law and a comprehensive food and drug law.

FDA's History (cont')

*FDA's origins as a federal consumer protection agency began with the passage of the **1906 Pure Food and Drugs Act**. This law was the culmination of about 100 bills over a quarter-century that aimed to rein in long-standing, serious abuses in the consumer product marketplace.*

Early analysis for mold in Ketchup:

Origins -1906

The passage of the 1906 Act was due in large part to the untiring scientific and political efforts of ***Harvey Washington Wiley****, who at the time was chief chemist of the Bureau of Chemistry of the U.S. Department of Agriculture, FDA's predecessor.*

The 1906 Act, which ***prohibited misbranded and adulterated food and drugs in interstate commerce****, charged the Bureau of Chemistry to carry out its provisions.*

Eventually, the position of Chief Chemist of the Bureau of Chemistry evolved into that of the Commissioner of Food and Drugs.

Origins -1930's

By the 1930s it was widely recognized that the Food and Drugs Act of 1906 was obsolete, but bitter disagreement arose as to what should replace it.

By 1937 most of the arguments had been resolved but Congressional action was stalled. Then came a shocking development--the deaths of more than 100 people after using a drug that was clearly unsafe.

1937:

New Hazards New Laws

Origins -1938

*The **1938 Food, Drug, and Cosmetic Act** tightened controls over drugs and food, included new consumer protection against unlawful cosmetics and medical devices, and enhanced the government's ability to enforce the law.*

This law, as amended, is still in force today.

Origins -1960's

Canad. Med. Ass. J.
April 21, 1962, vol. 86

CASE REPORTS

Association of Thalidomide (Kevadon) With Congenital Anomalies

A. E. RODIN, M.D., F.R.C.P.[C],* L. A. KOLLER, M.D.† and J. D. TAYLOR, Ph.D.,‡ *Edmonton, Alta.*

ALTHOUGH the induction of congenital anomalies by prenatal drug administration has been accomplished experimentally,[1, 2] the occurrence of this phenomenon in humans has not been proved, even though it has been suspected in the case of tolbutamide and aminopterin.[3] Since December 2, 1961, however, several letters to the editor of the *Lancet* have reported a relatively high incidence of abnormalities in infants of mothers treated with a "non-toxic" sedative, thalidomide (Contergan, Distaval), during the first two months of pregnancy.[4-6] The anomalies include limb defects predominantly, but also cardiac and gastrointestinal anomalies. Recently 10 cases of gross limb defects have been reported from one nursery unit in Scotland in a period of one year.[7] Eight of the mothers are known to have received thalidomide (Distaval), and it was suggested that the other two, as well

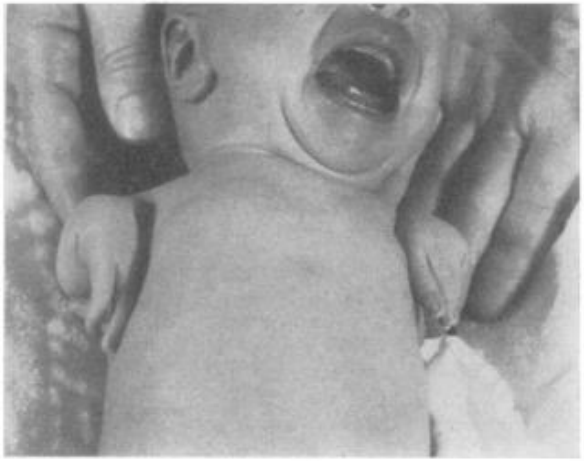


Fig. 1

Kevadon (or better known by its generic name, Thalidomide) was a widely used drug in the 1950s to support sleep and to treat nausea in pregnant women.

Origins -1960

***Frances Oldham Kelsey**, a medical officer at the Food and Drug Administration in Washington, who raised concerns about thalidomide before its effects were conclusively known.*

For a critical 19-month period, she fastidiously blocked its approval while drug company officials maligned her as a bureaucratic nitpicker.

Origins -1962

*The **Kefauver-Harris Amendments of 1962**, which were inspired by the Thalidomide tragedy in Europe (and the FDA's vigilance that prevented the drug's marketing in the United States), strengthened the rules for drug safety and required manufacturers to prove their drugs' effectiveness.*

Origins -1970's

1972 – 1973: Pacemaker failures reported

1975: Congressional Hearing - Dalkon Shield intrauterine device caused thousands of injuries.

Class I, II, and III Medical Devices defined based on degree of control necessary to be safe and effective.

Origins -1976

President Gerald Ford signs the Medical Device Amendments Act of 1976

The Medical Device Amendments of 1976 followed a U.S. Senate finding that faulty medical devices had caused 10,000 injuries, including 731 deaths. The law applied safety and effectiveness safeguards to new devices.

FDA - 2009

*The **Family Smoking Prevention and Tobacco Control Act** (Tobacco Control Act), signed into law on June 22, 2009, gives FDA authority to regulate the manufacture, distribution, and marketing of tobacco products.*

It puts in place specific restrictions on marketing tobacco products to children and gives FDA authority to take further actions to protect public health.

FDA - 2010

*The **Affordable Care Act** explicitly states that manufacturers and authorized distributors must submit the following information concerning drug sample distribution to FDA:*

(1) the identity and quantity of drug samples requested;
(2) the identity and quantity of drug samples distributed;
(3) the name, address, professional designation, and signature of any person who makes or signs for the request, and
(4) any other category of information determined appropriate by the Secretary.

FDA - 2011

*The **FDA Food Safety Modernization Act (FSMA)**, the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011.*

It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

FDA - 2012

*The **Food and Drug Administration Safety and Innovation Act** (FDASIA), signed into law on July 9, 2012, expands the FDA's authorities and strengthens the agency's ability to safeguard and advance public health by:*

1) *Giving the authority to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biological products;*
2) *Promoting innovation to speed patient access to safe and effective products;*
3) *Increasing stakeholder involvement in FDA processes; and*
4) *Enhancing the safety of the drug supply chain.*

FDA - 2013

*The **Drug Quality and Security Act** (DQSA), was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. This will enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.*

Additionally, the DSCSA directs FDA to establish national licensure standards for wholesale distributors and third-party logistics providers, and requires these entities report licensure and other information to FDA annually.

FDA - 2016

*The **21st Century Cures Act** (Cures Act), signed into law on December 13, 2016, is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.*

The law builds on FDA's ongoing work to incorporate the perspectives of patients into the development of drugs, biological products, and devices in FDA's decision-making process. Cures enhances our ability to modernize clinical trial designs and clinical outcome assessments, which will speed the development and review of novel medical products, including medical countermeasures.

FDA - 2017

Generic drug user fees make it possible for FDA and industry to continue to ensure that the American public has access to safe and high quality generic drugs and generic drug products.

The implementation of the ***Generic Drug User Fee Amendments*** *(GDUFA) encompasses a wide range of activities that fall within the scope of regulating the generic drug industry. GDUFA was reauthorized on August 18, 2017 (GDUFA II), with provisions that went into effect October 1, 2017 and remain in effect through September 30, 2022.*

FDA Guidance Documents

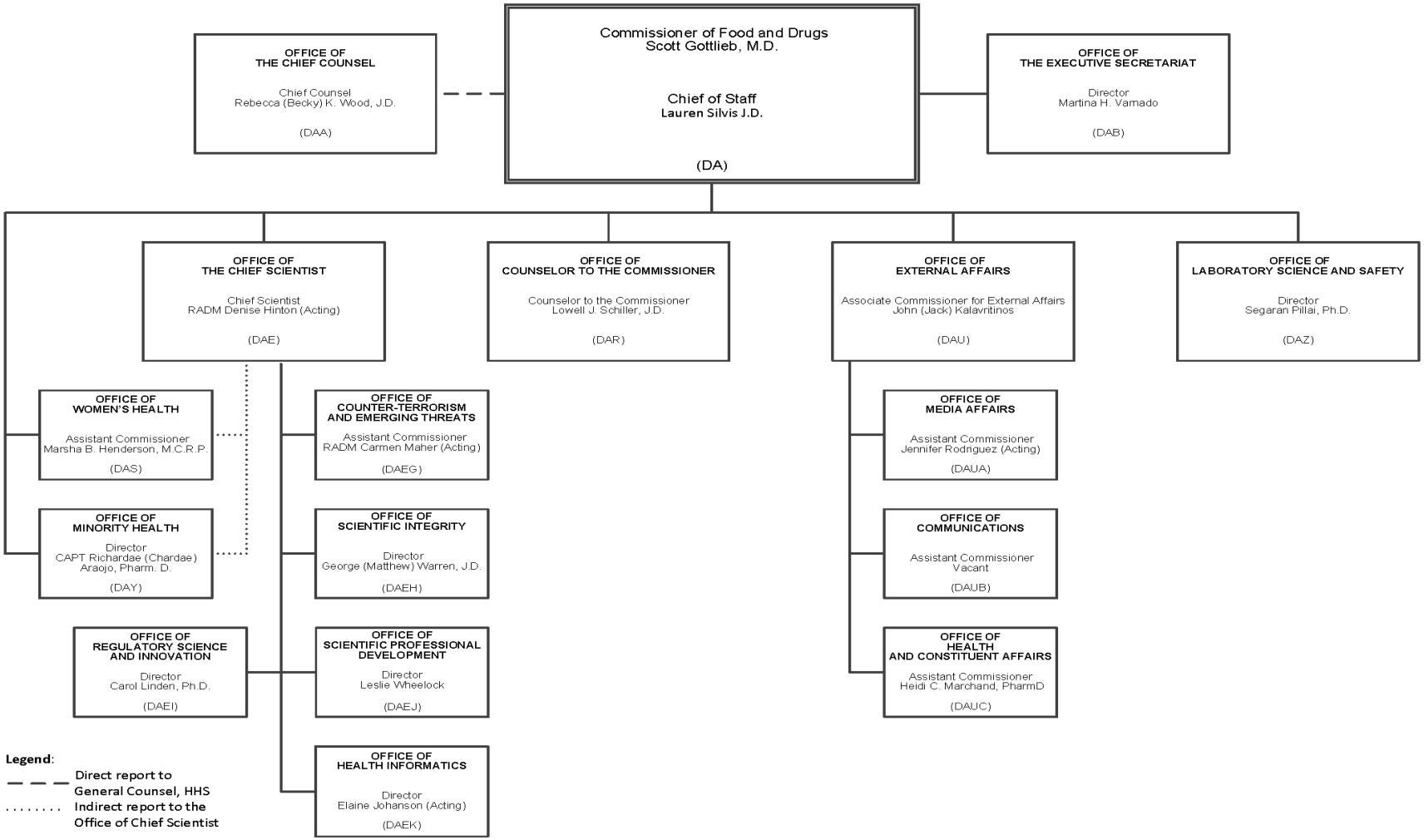
Guidance documents represent FDA's current thinking on a topic.

They do not create or confer any rights for or on any person and do not operate to bind FDA or the public.

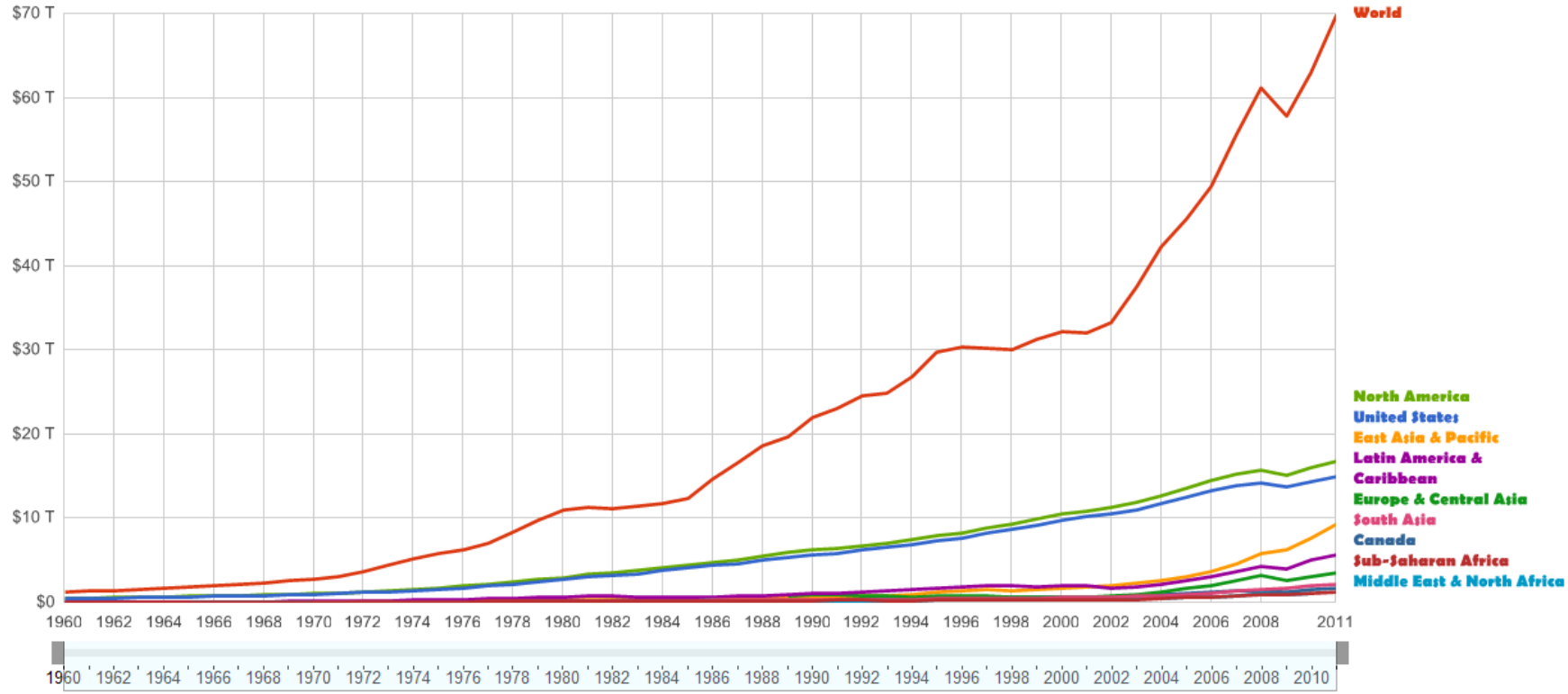
You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

Approved by the FDA Reorganization Coordinator
& Principal Delegation Control Officer
18 January 2017

FOOD AND DRUG ADMINISTRATION
OFFICE OF THE COMMISSIONER

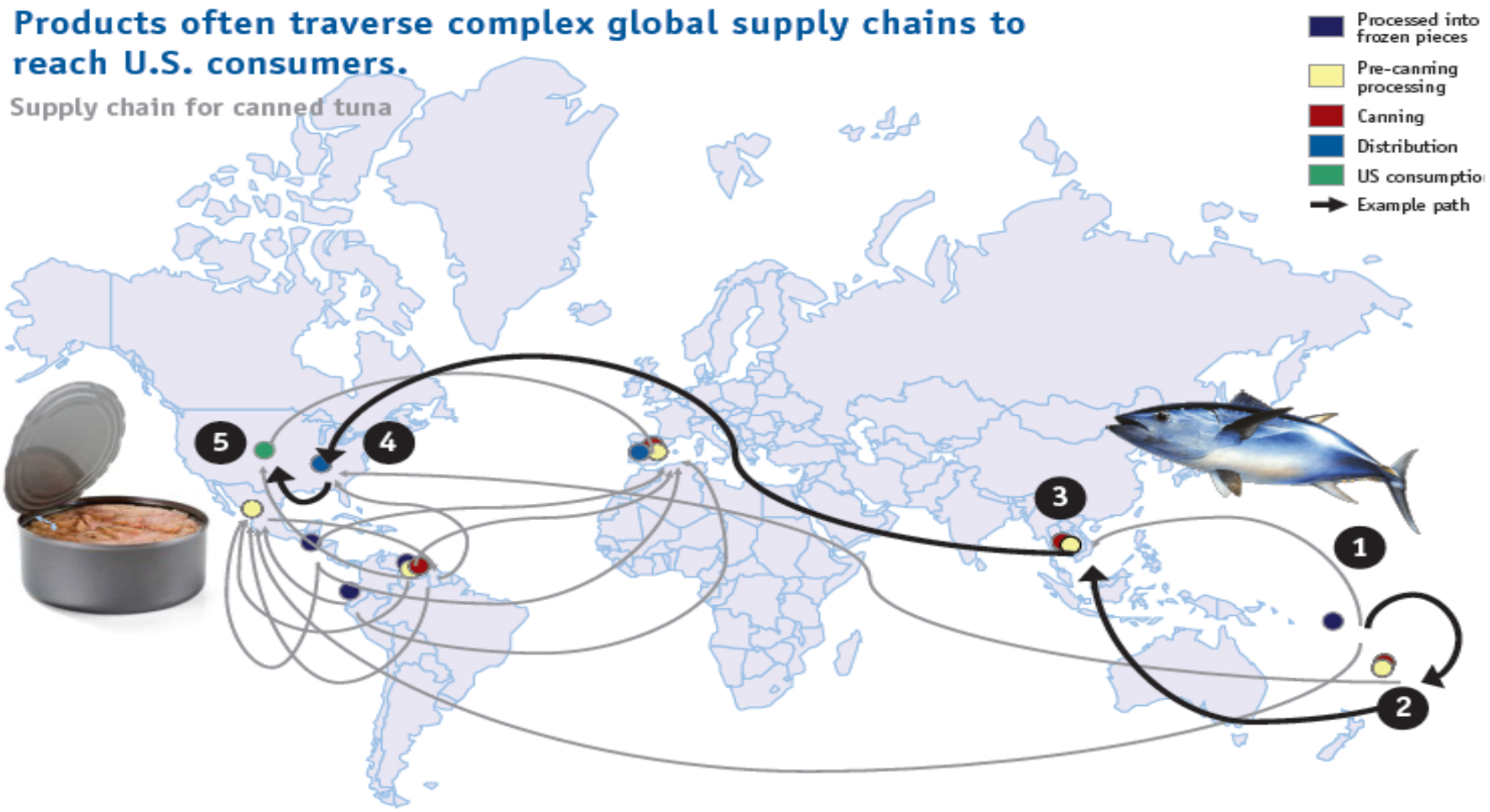


Gross Domestic Product - Global



Data from World Bank Last updated: Oct 31, 2012

Illustrative Global Supply Chain for Canned Tuna

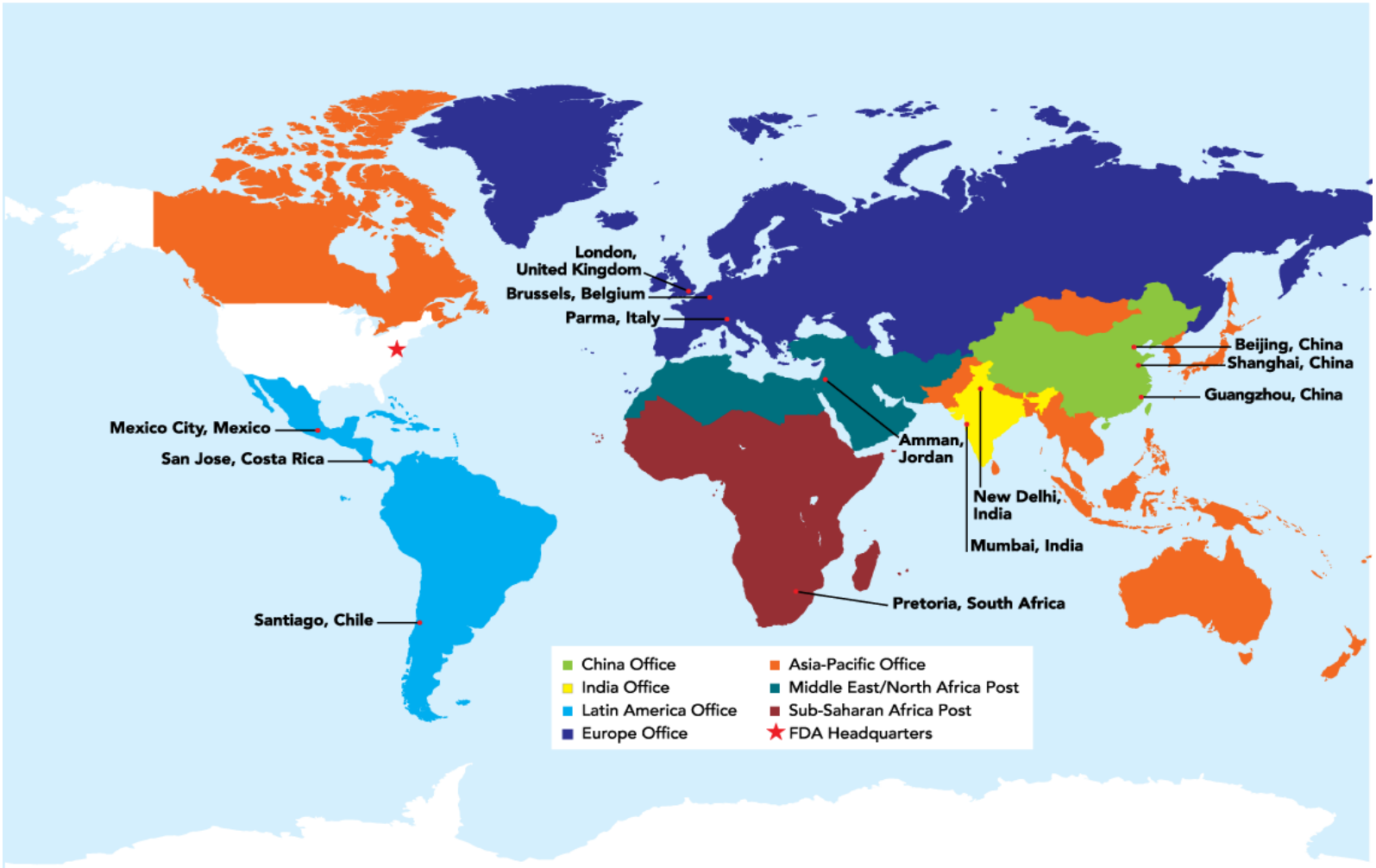


Source: http://www.ilo.org/public/english/dialogue/sector/techmeet/tmfce07/tmfce-r.pdf

Global Strategy

- Partner with foreign counterparts to create global coalitions of regulators focused on ensuring and improving global product safety.
- Work with these coalitions to build a global data-information system and network and proactively share data with peers.
- Expand capabilities in intelligence gathering and use, with an increased focus on risk analytics and modernized IT capabilities.
- Allocate agency resources effectively based on risk, leveraging the combined efforts of other government.

Global: FDA Foreign Offices



Globalization efforts

- Work to partner with foreign counterparts to create global coalitions of regulators.
- Member of Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) since January of 2011
  - Annual sharing of surveillance inspections for the year
- Mutual Recognition Effort with EU
- Share specific information on planned inspections
  - Since October 1, 2014
    - » Foreign regulators accompanied on 30 drug inspections

FDA's Office of Regulatory Affairs Aligns for the Future

What

Why

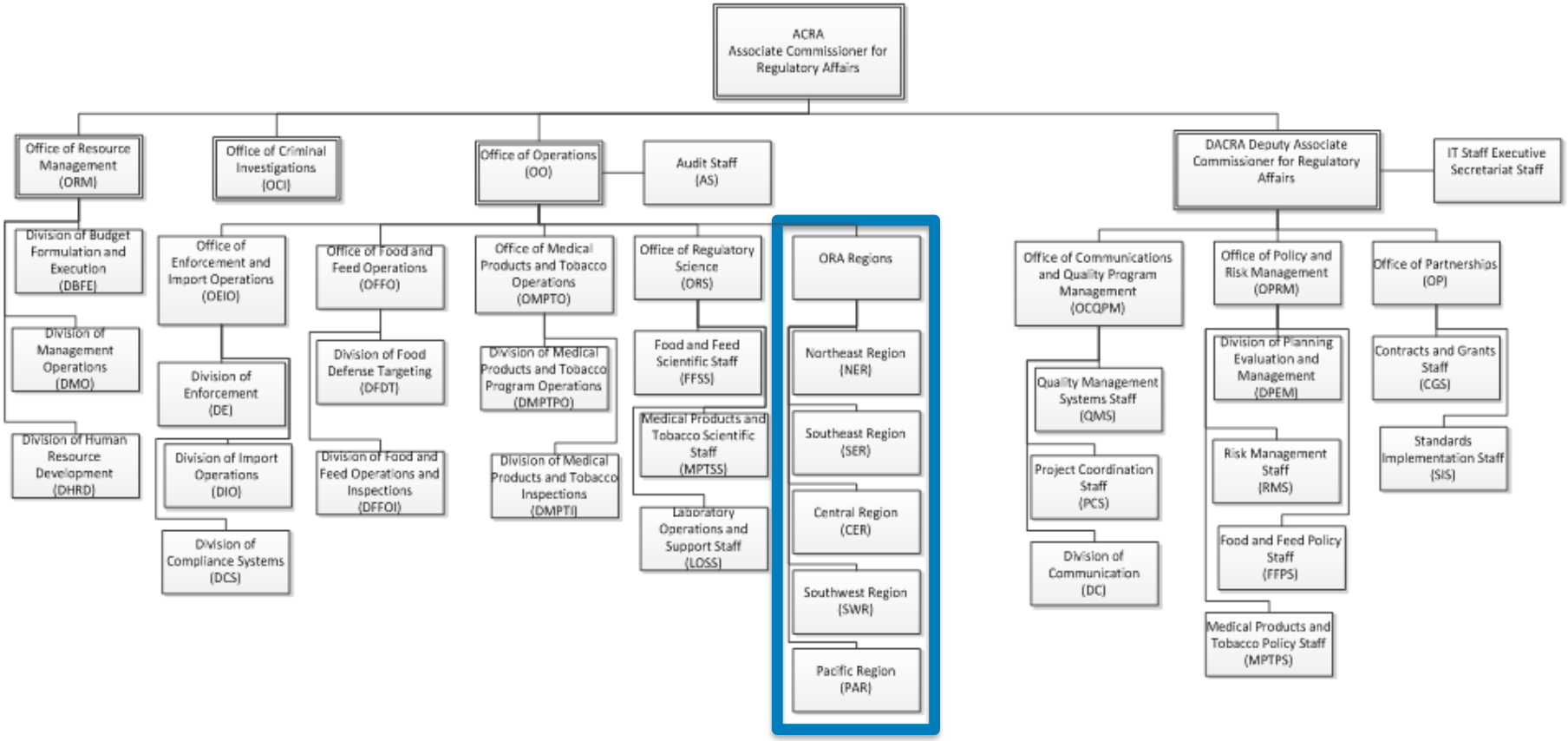
How

“…Modernize and strengthen the FDA workforce to improve public health response.”

2013 FDA Program Alignment Charge

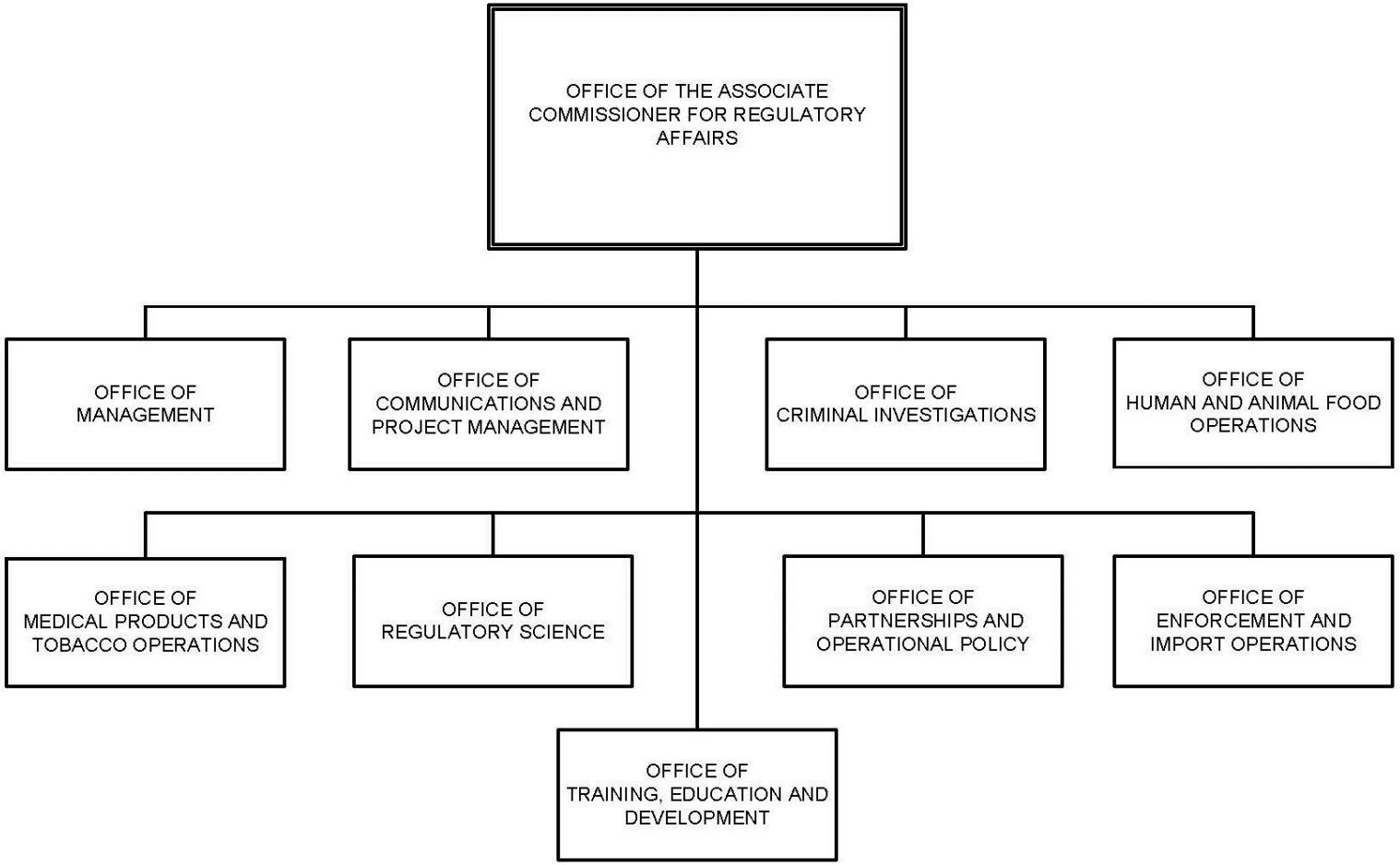
OLD

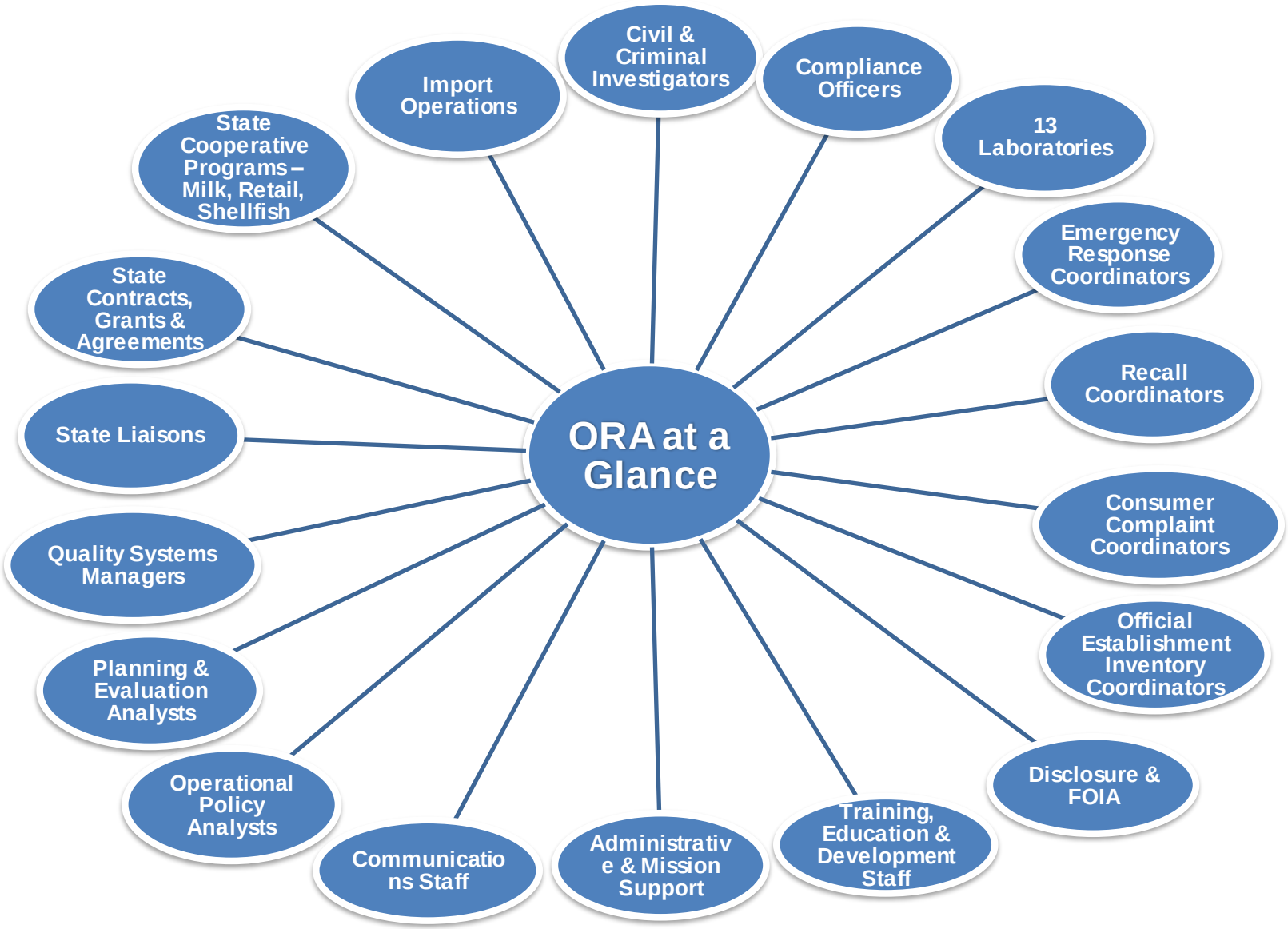
Geographically Aligned Organizational Model



New

Program Aligned Organizational Model




ORA at a Glance
Civil & Criminal Investigators
Compliance Officers
13 Laboratories
Emergency Response Coordinators
Recall Coordinators
Consumer Complaint Coordinators
Official Establishment Inventory Coordinators
Disclosure & FOIA
Training, Education & Development Staff
Administrative & Mission Support
Communications Staff
Operational Policy Analysts
Planning & Evaluation Analysts
Quality Systems Managers
State Liaisons
State Contracts, Grants & Agreements
State Cooperative Programs – Milk, Retail, Shellfish
Import Operations

Program Alignment: Key Changes

From	To
Geographic management of operations	Program management of operations, management teams based on staff: • Bioresearch Monitoring — 2 management teams • Biologics — 2 management teams • Human and Animal Food — 12 management teams • Medical Device and Radiological Health — 3 management teams • Pharmaceutical Quality — 4 management teams • Tobacco • Plus Imports as a program — 5 management teams
SES Regional Food & Drug Directors	SES Program Directors
Degrees of program specialization for investigations, compliance and operational managers	Exclusive specialization in one program for investigations, compliance and operational managers
20 District Directors who manage the geographic district and all programs operations within the district	20 District Directors who manage the geographic district and only one program for operations. Plus eight new program division directors who manage program operations only – total 28 management teams
One import district and a range of import operations embedded within the 16 other districts	Five import divisions (four new import divisions) covering all borders, managing import operations nationally as a program

Program Alignment: Key Changes

From	To
13 labs reporting into the regions	National Lab Management - 13 labs reporting into ORA's Office of Regulatory Science with three additional directors managing separate program operations
Division of Human Resource Development within the Office of Resource Management	Office of Training, Education and Development
State Cooperative Programs decentralized across five regions – shellfish, milk, retail	Office of State Cooperative Programs under the Human and Animal Food Operations, as a single national program(s)
Functions based in geography: consumer complaint coordinators, state liaisons, emergency response coordinators	Retain certain functions based in geography: consumer complaint coordinators, state liaisons, emergency response coordinators
Functions decentralized local reporting: Freedom of Information (FOI) staff, industrial hygienists (IH), and administrative staff	Staff remain embedded locally, but report into a single office: FOI staff report into Division of Information Disclosure; IHs report into the Office of Regulatory Science; administrative staff report into the Office of Management

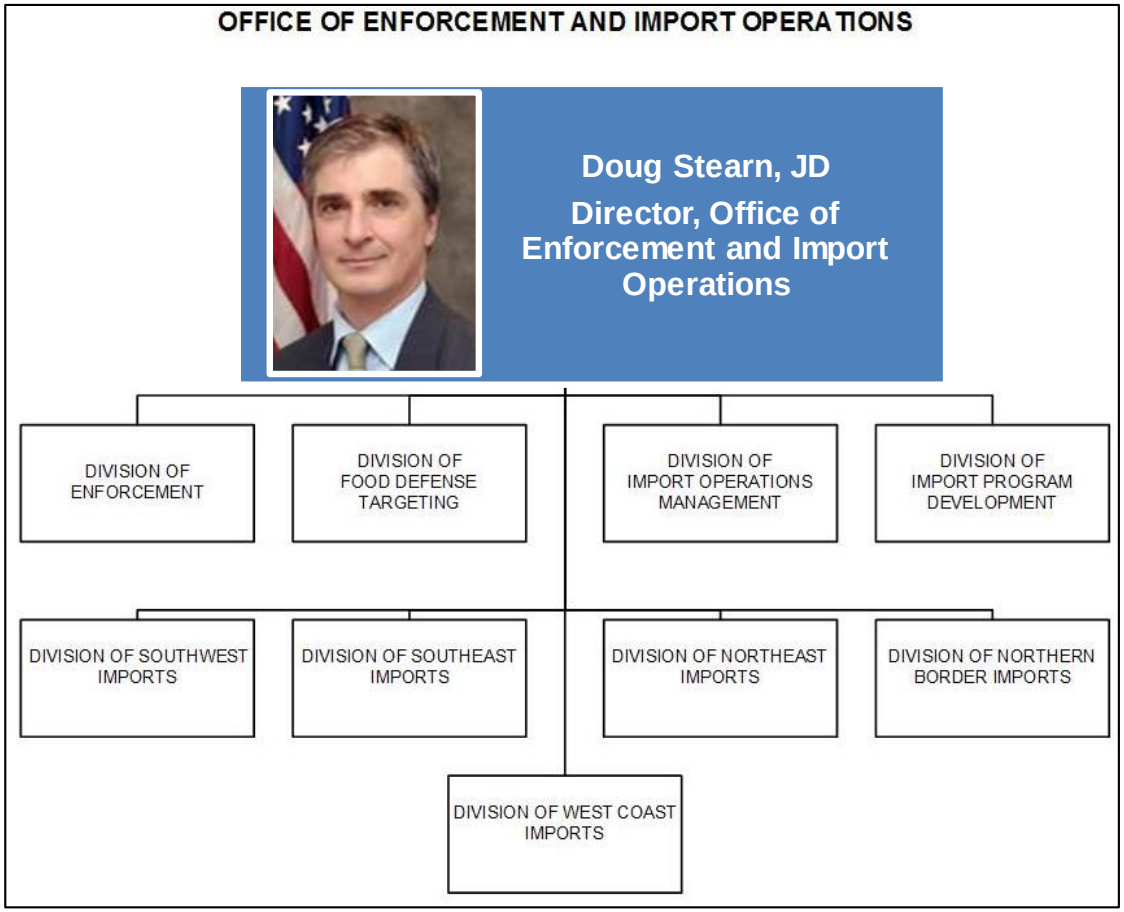
Offices of…

Melinda Plaisier, MSW
Associate Commissioner for Regulatory Affairs

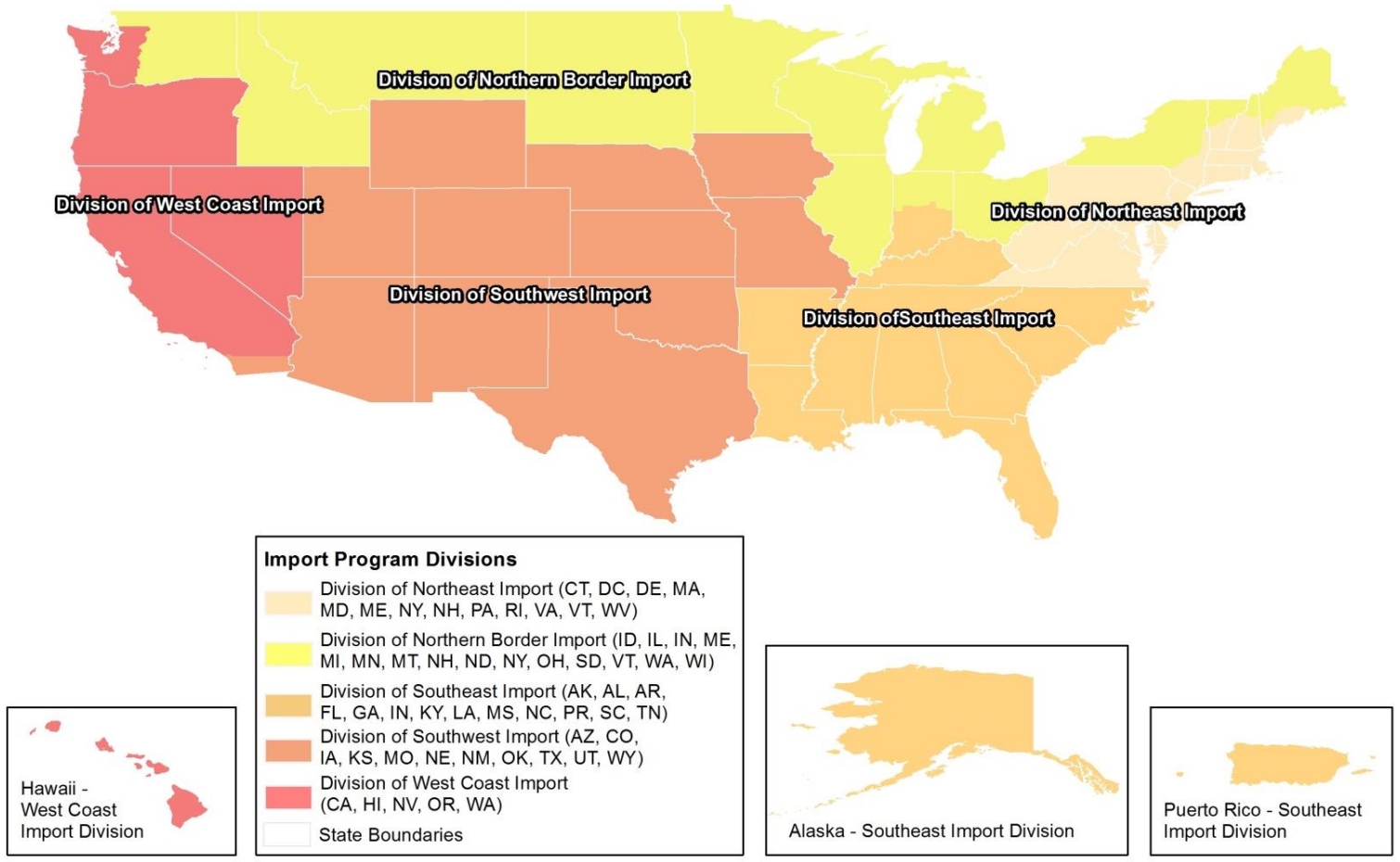
Doug Stearn, JD
Director, Office of Enforcement and Import Operations

Paul Norris, DVM, MPA
Director, Office of Regulatory Science

Office of Enforcement and Import Operations



Office of Enforcement and Import Operations

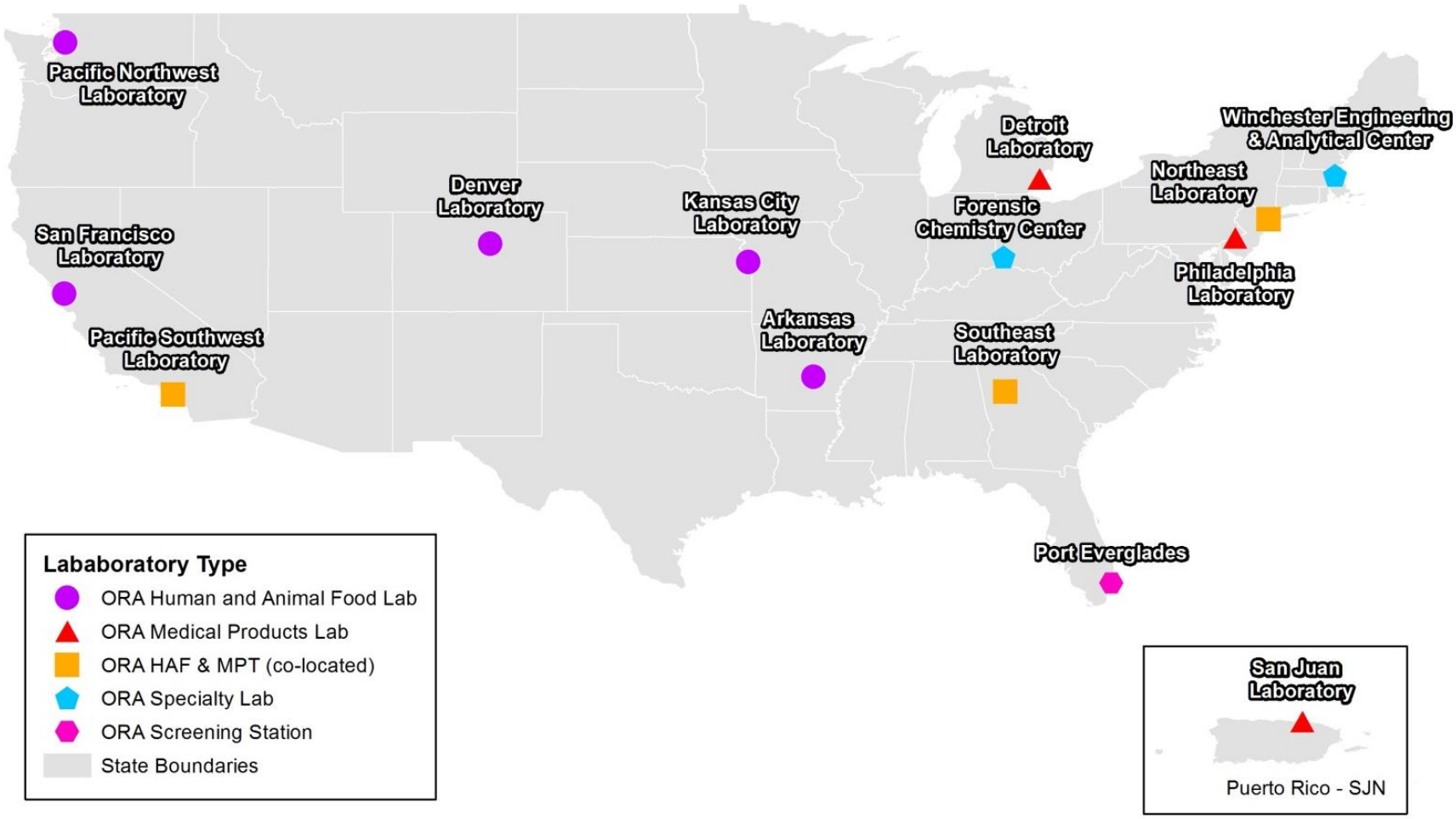


Office of Regulatory Science

Paul Norris, DVM, MPA
Director, Office of Regulatory Science

- Office of Medical Products, Tobacco and Specialty Laboratory Operations
  Medical Products and Tobacco Scientific Staff
  - Forensic Chemistry Center
  - Winchester Engineering Analytical Center
  - Detroit Laboratory
  - Northeast Medical Products Laboratory
  - Pacific Southwest Medical Products Laboratory
  - Philadelphia Laboratory
  - San Juan Laboratory
  - Southeast Tobacco Laboratory
- Office of Food and Feed Laboratory Operations
  Food and Feed Scientific Staff
  - Arkansas Laboratory
  - Denver Laboratory
  - Kansas City Laboratory
  - Northeast Food and Feed Laboratory
  - Pacific Northwest Laboratory
  - San Francisco Laboratory
  - Southeast Food and Feed Laboratory
  - Pacific Southwest Food and Feed Laboratory
- Office of Research Coordination and Evaluation

Office of Regulatory Science

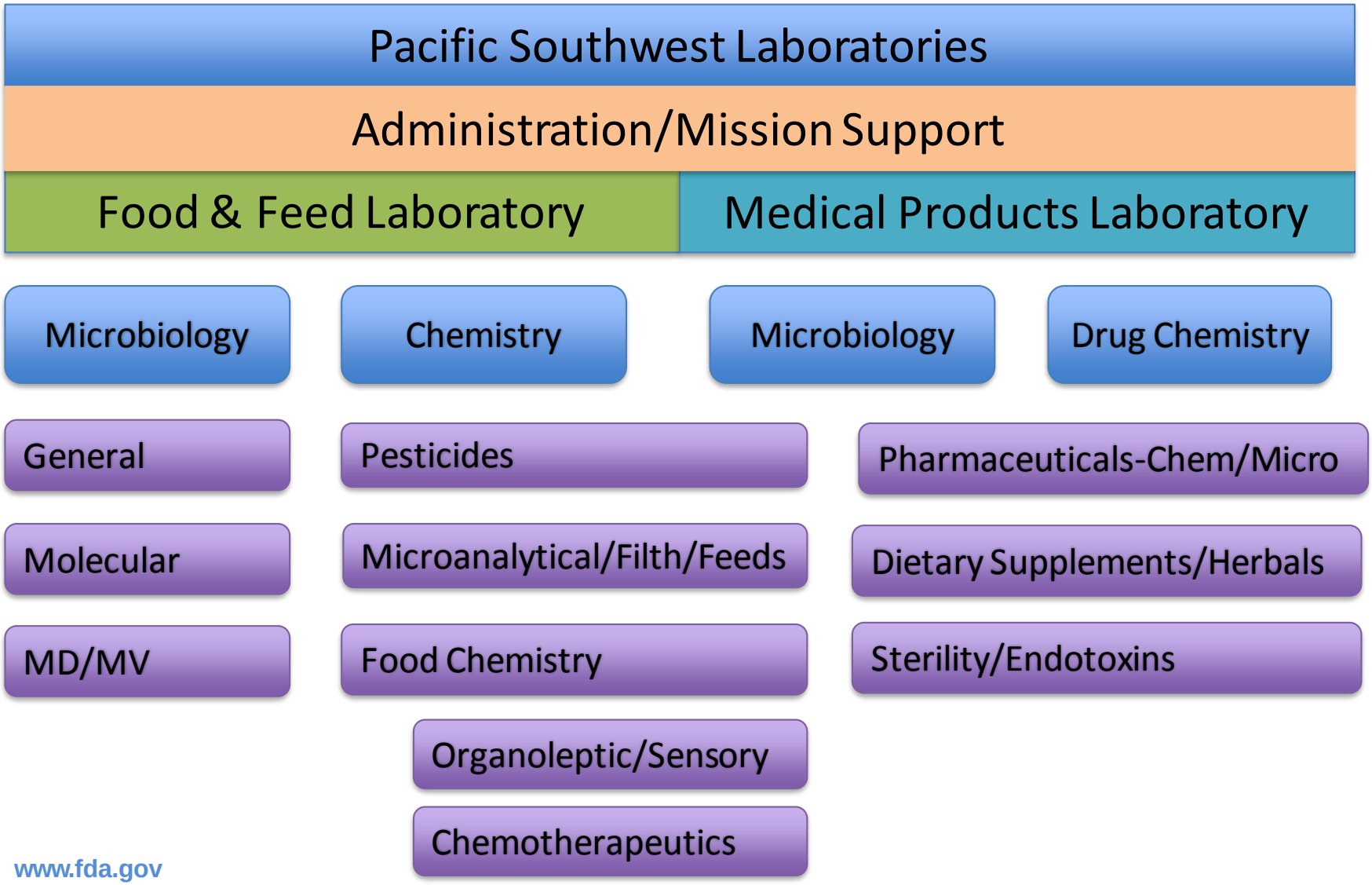


Role of the Regulatory Laboratories

- Surveillance Testing
- Compliance (for cause) Testing
- Targeted surveys
- Provide technical assistance on inspections
- Regulatory method development

Mission Statement:

ORA's laboratory network provides diverse scientific expertise, leadership, and responsive quality analytical services to safe guard public health in a global environment.


Pacific Southwest Laboratories
Administration/Mission Support
Food & Feed Laboratory
Medical Products Laboratory
Microbiology
Chemistry
Microbiology
Drug Chemistry
General
Pesticides
Pharmaceuticals-Chem/Micro
Molecular
Microanalytical/Filth/Feeds
Dietary Supplements/Herbals
MD/MV
Food Chemistry
Sterility/Endotoxins
Organoleptic/Sensory
Chemotherapeutics

Chemistry

- Standard Testing includes:
  - Pesticides
  - Decomposition of Seafoods
  - Filth, Sanitation & Prohibited Materials in Regulated Products
  - Metals in Ceramic Ware
  - Herbal Products/Dietary Supplements
  - Chemotherapeutics in Seafood
  - Surgical Gloves & Condoms
  - Pharmaceuticals – Bulk ingredients/finished products

Microbiology

- Standard Testing includes:
  - *Salmonella*
  - *Listeria*
  - *Vibrio* species including toxigenic species
  - *Escherichia* coli O157:H7
  - *Staphylococcus* aureus and associated toxin
  - *Escherichia* coli and Coliforms
  - Alkaline Phosphatase (Cheese)
  - pH/Aw

Emergency Response

- Food Borne Outbreaks
  - Respond to *E*. coli O157:H7 (EHEC), *Listeria* monocytogenes, and *Salmonella*.
  - Bioterrorism Preparedness
    - Food Defense
    - BSL3 laboratory intentional contamination of food products.
    - In collaboration with the Food Emergency Response Network (FERN), Laboratory Response Network (LRN), Select Agent Program (CDC), and State Public Health Labs.

Laboratory Networks

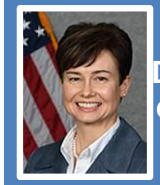
- **Food Emergency Response Network**
- **Laboratory Response Network**
- **National Animal Health Laboratory Network**
- **National Plant Diagnostic Network**
- **Environmental Network**

Office of Medical Products and Tobacco Operations

Ellen Morrison
Assistant Commissioner
Office of Medical Products and Tobacco Operations

Director
Tobacco Staff
[vacant]

Ginette Michaud, MD
Director, Office of Biological Products Operations



Chrissy Cochran, PhD
Director, Office of Bioresearch Monitoring Operations

Jan Welch
Director, Office of Medical Device and Radiological Health Operations

Alonza Cruse
Director, Office of Pharmaceutical Quality Operations

Office of Biological Products Operations

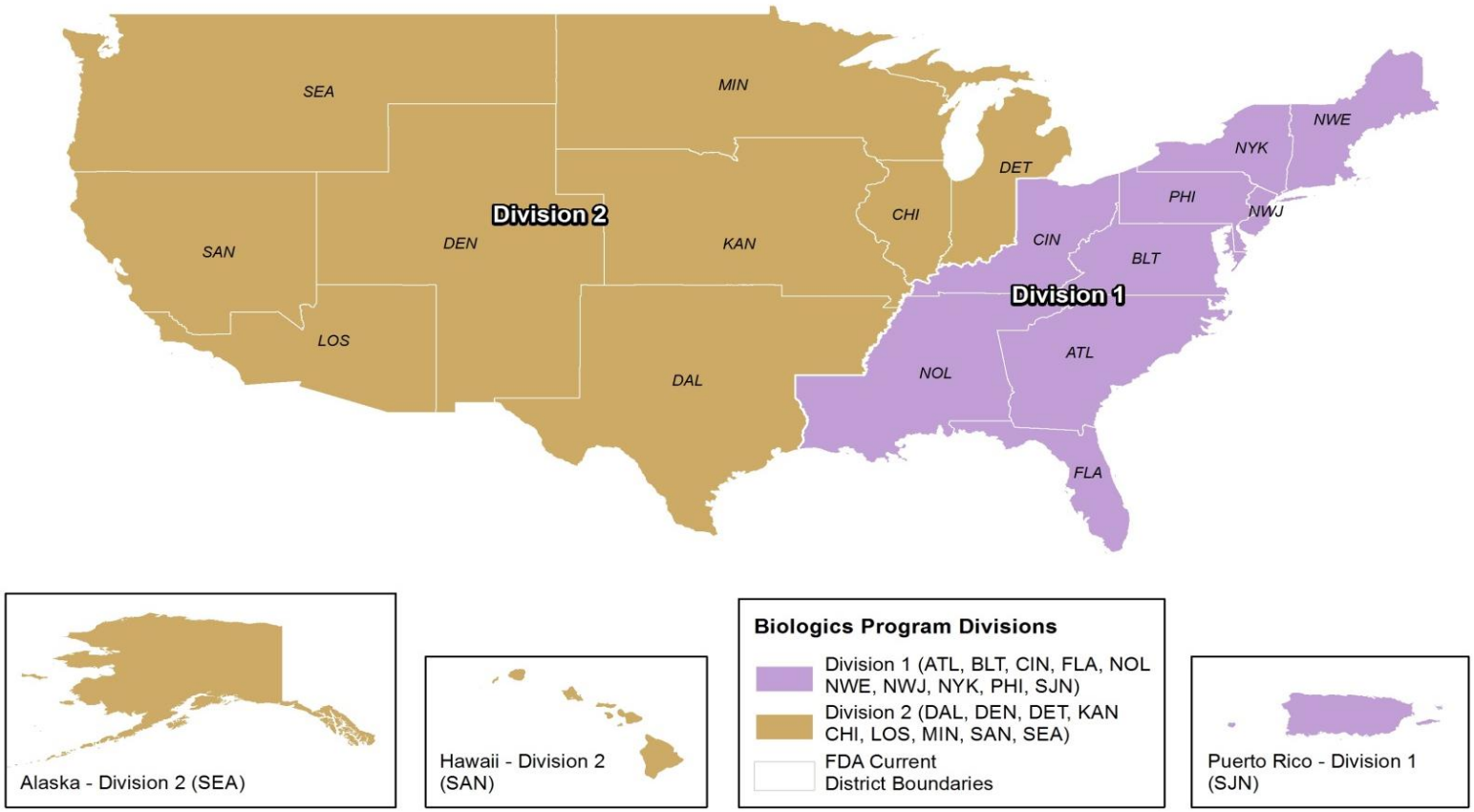
OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS
OFFICE OF BIOLOGICAL PRODUCTS OPERATIONS

Ginette Michaud, MD
Director, Office of Biological Products Operations

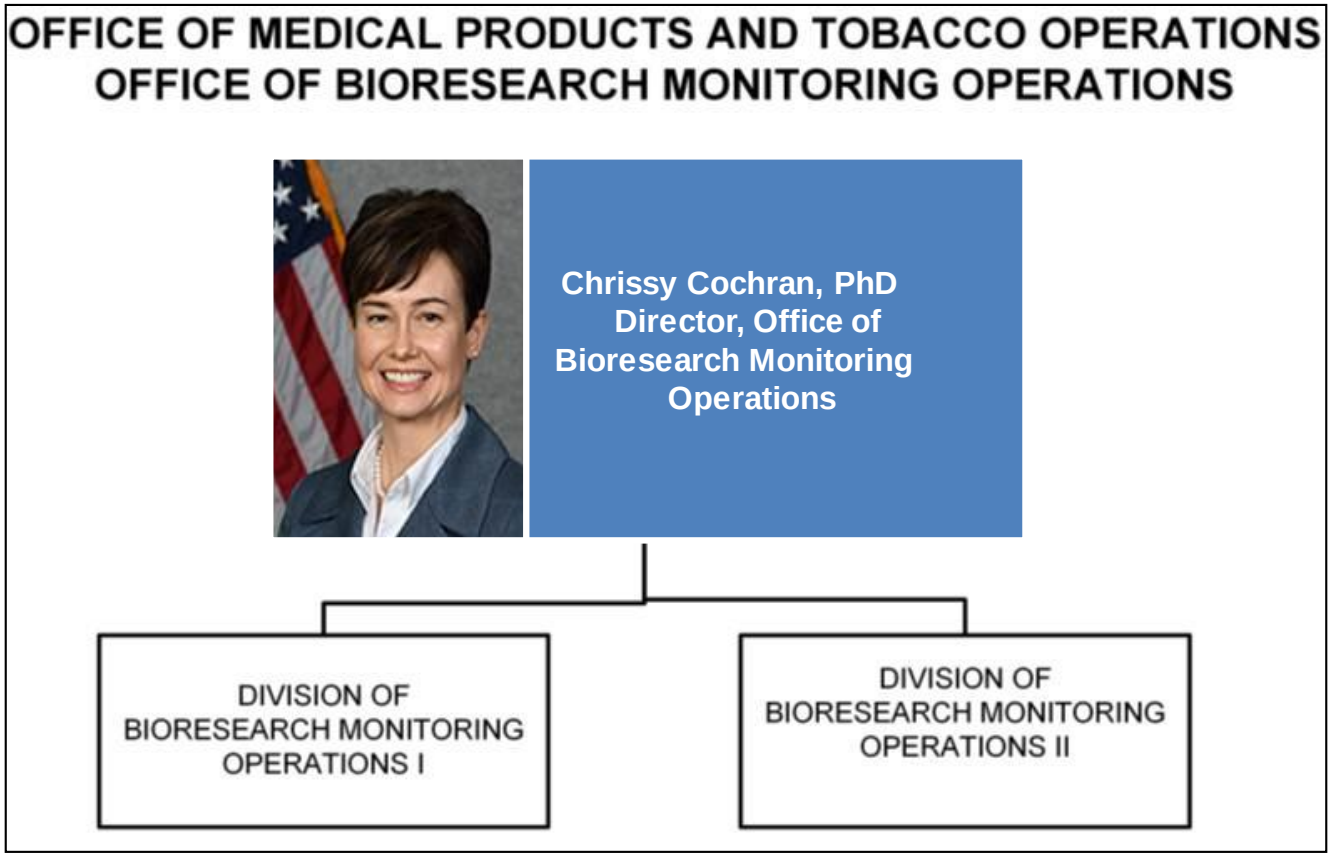
DIVISION OF BIOLOGICAL PRODUCTS OPERATIONS I

DIVISION OF BIOLOGICAL PRODUCTS OPERATIONS II

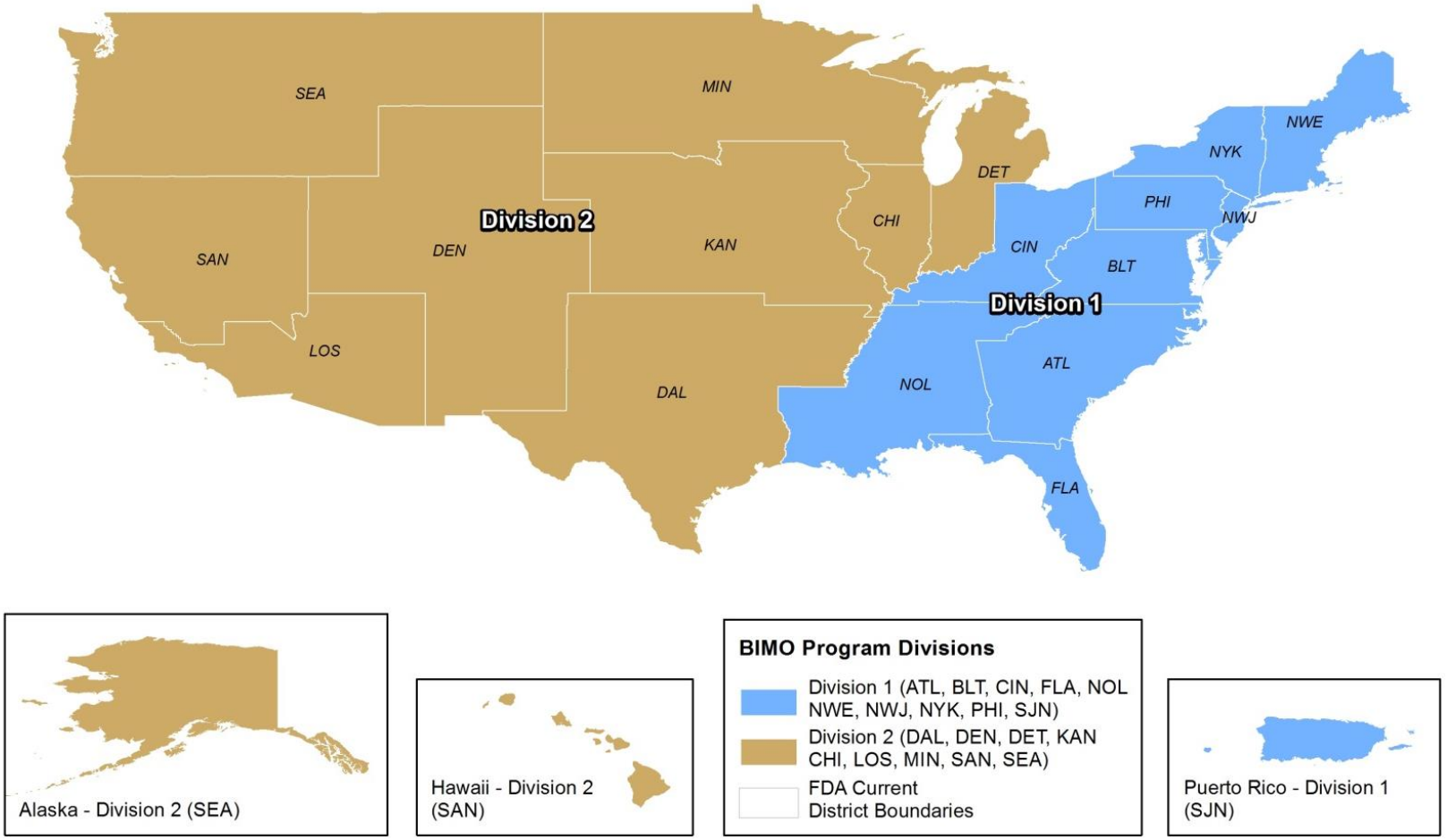
Office of Biological Products Operations



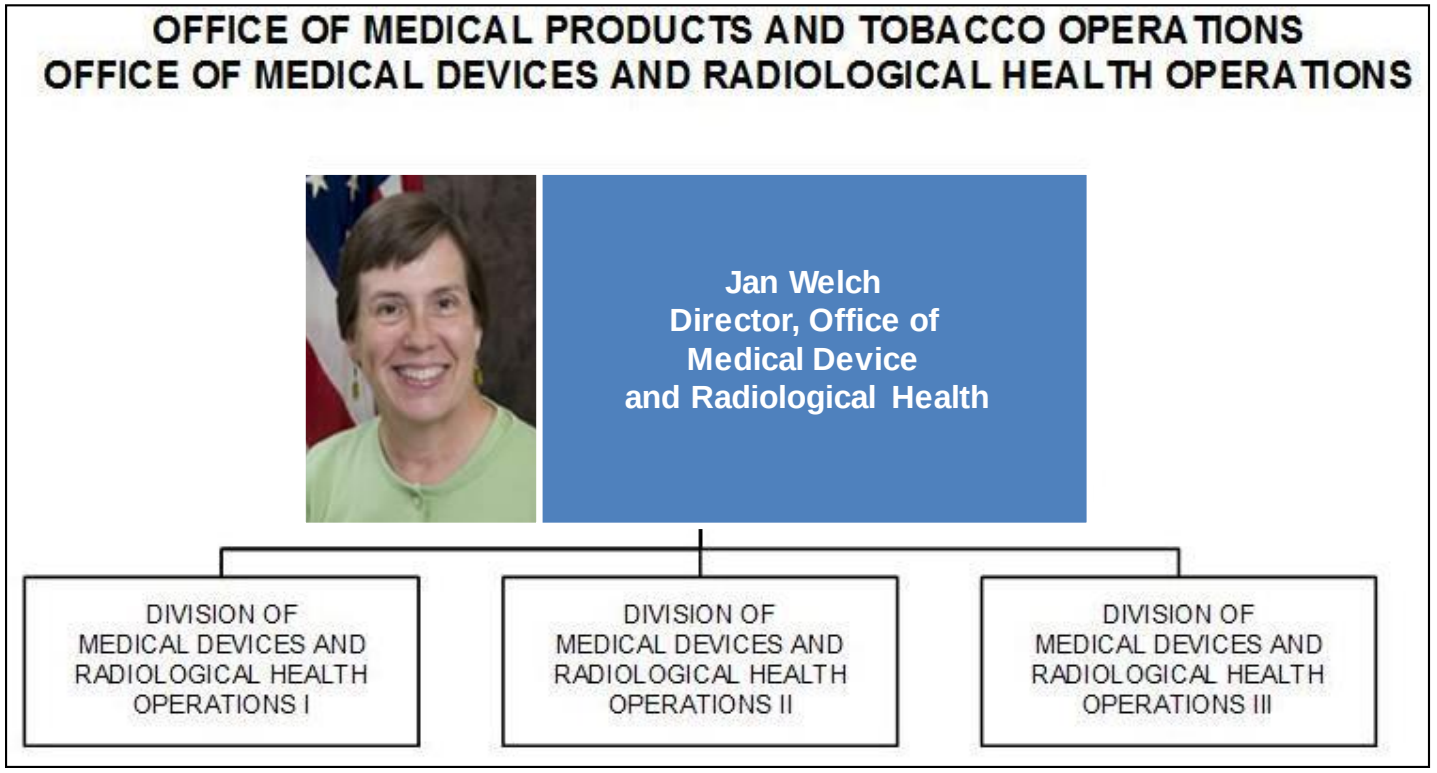
Office of Bioresearch Monitoring Operations



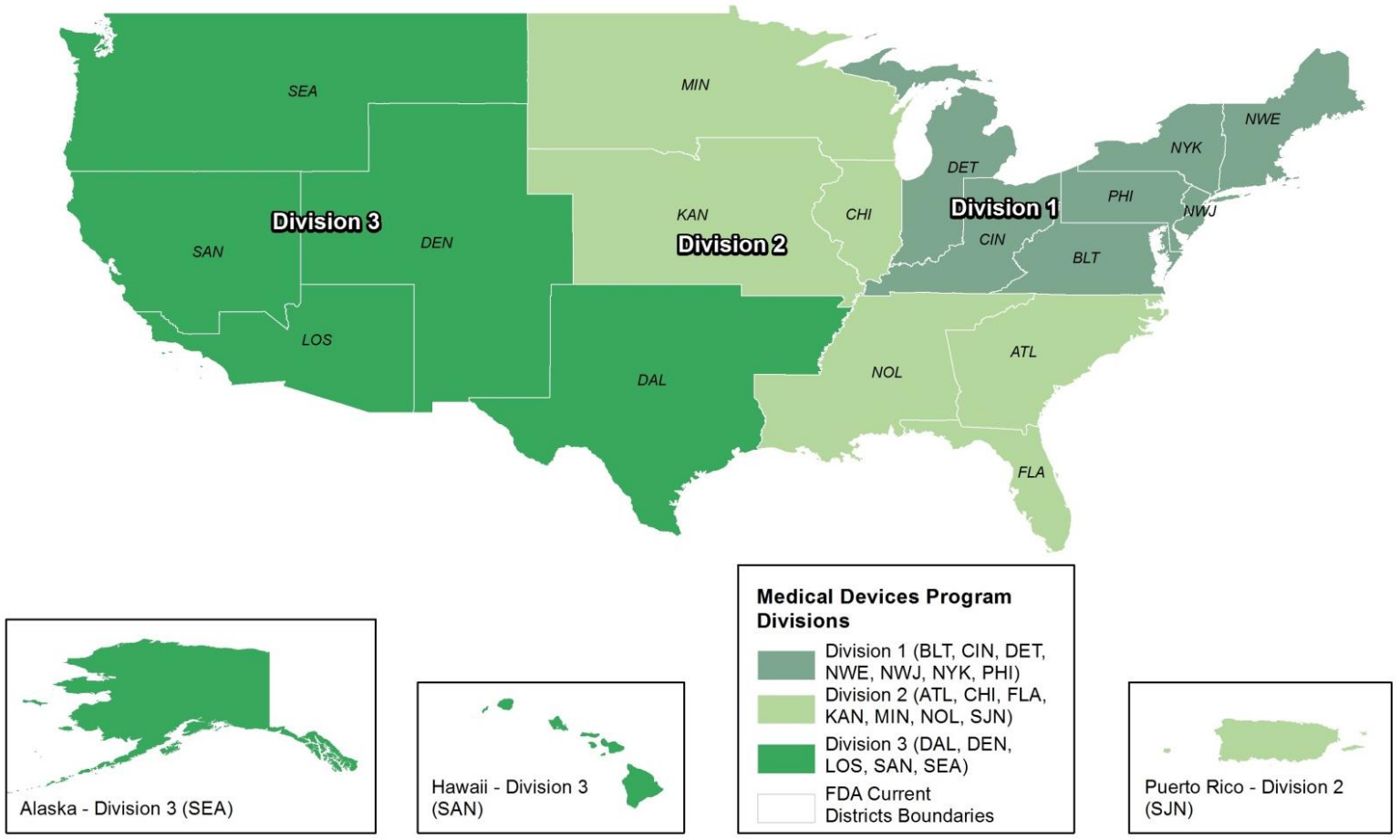
Office of Bioresearch Monitoring Operations



Office of Medical Device and Radiological Health Operations



Office of Medical Device and Radiological Health Operations



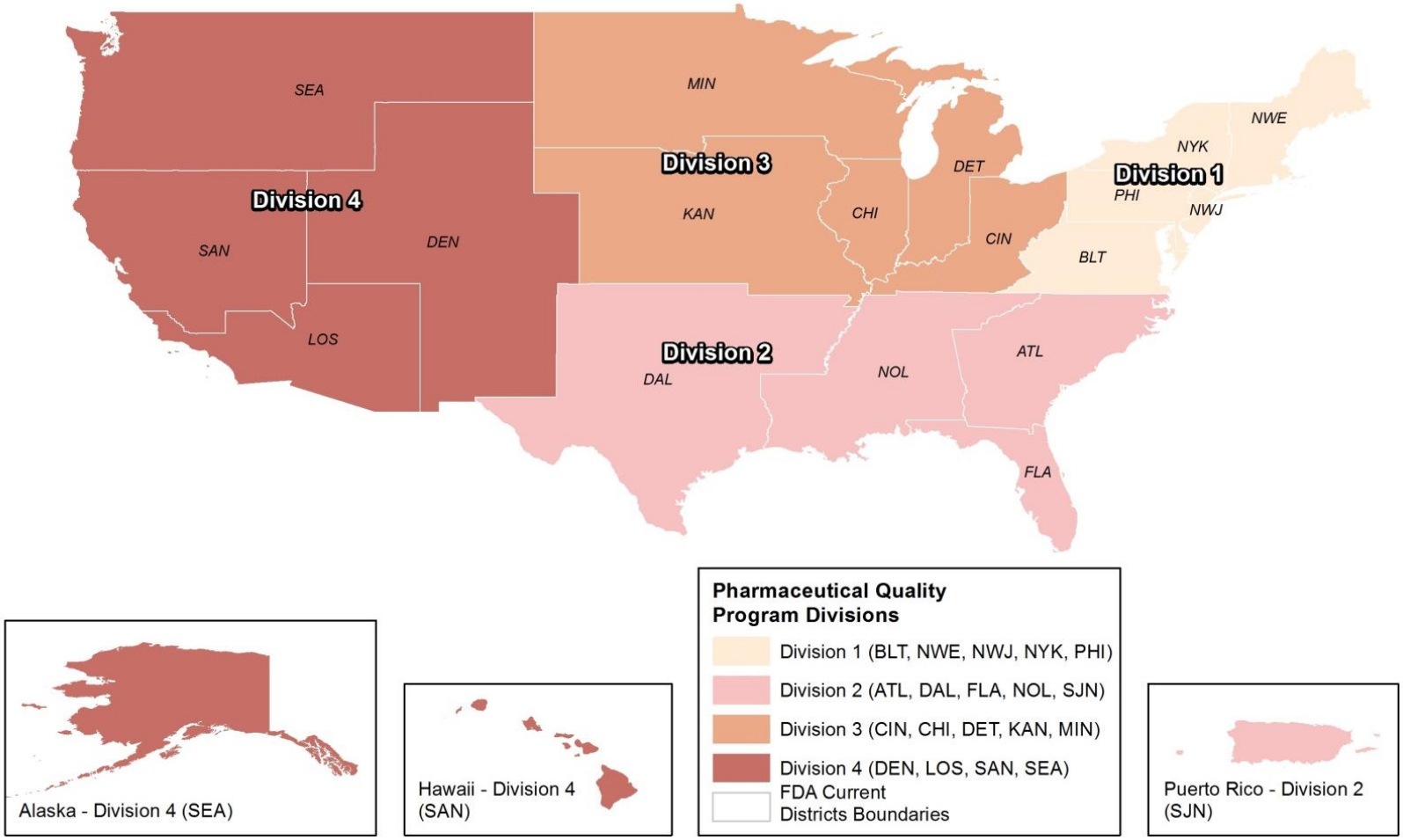
Office of Pharmaceutical Quality Operations

OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

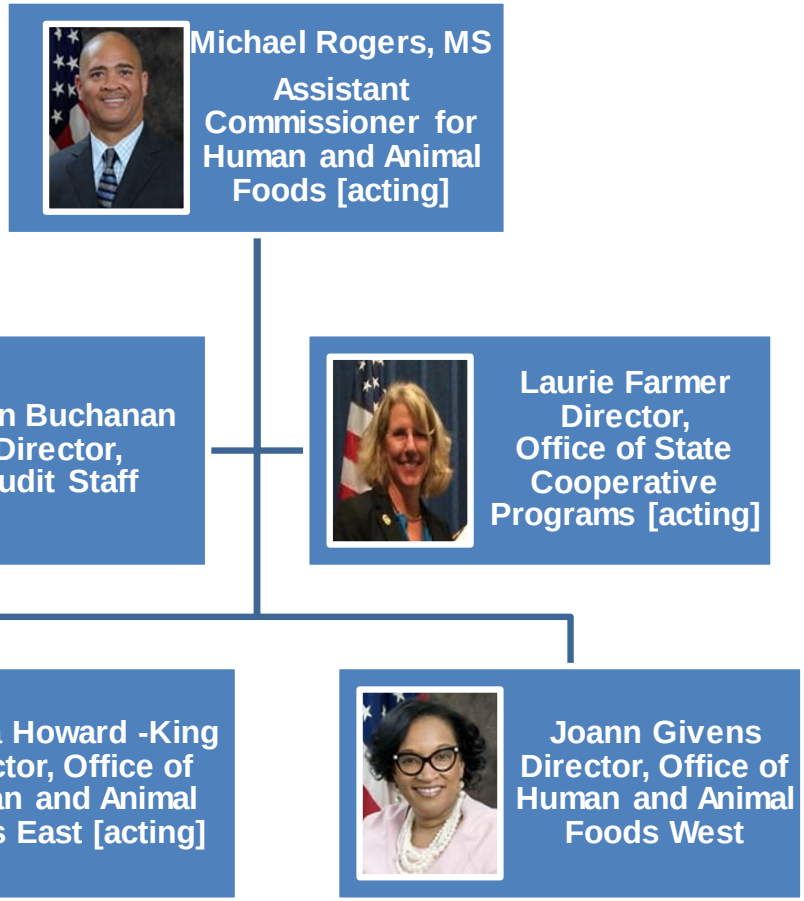
Alonza Cruse
Director, Office of Pharmaceutical Quality Operations

- DIVISION OF PHARMACEUTICAL QUALITY OPERATIONS I
- DIVISION OF PHARMACEUTICAL QUALITY OPERATIONS II
- DIVISION OF PHARMACEUTICAL QUALITY OPERATIONS III
- DIVISION OF PHARMACEUTICAL QUALITY OPERATIONS IV
- DIVISION OF PHARMACEUTICAL QUALITY PROGRAMS
- DIVISION OF FOREIGN PHARMACEUTICAL QUALITY INSPECTIONS

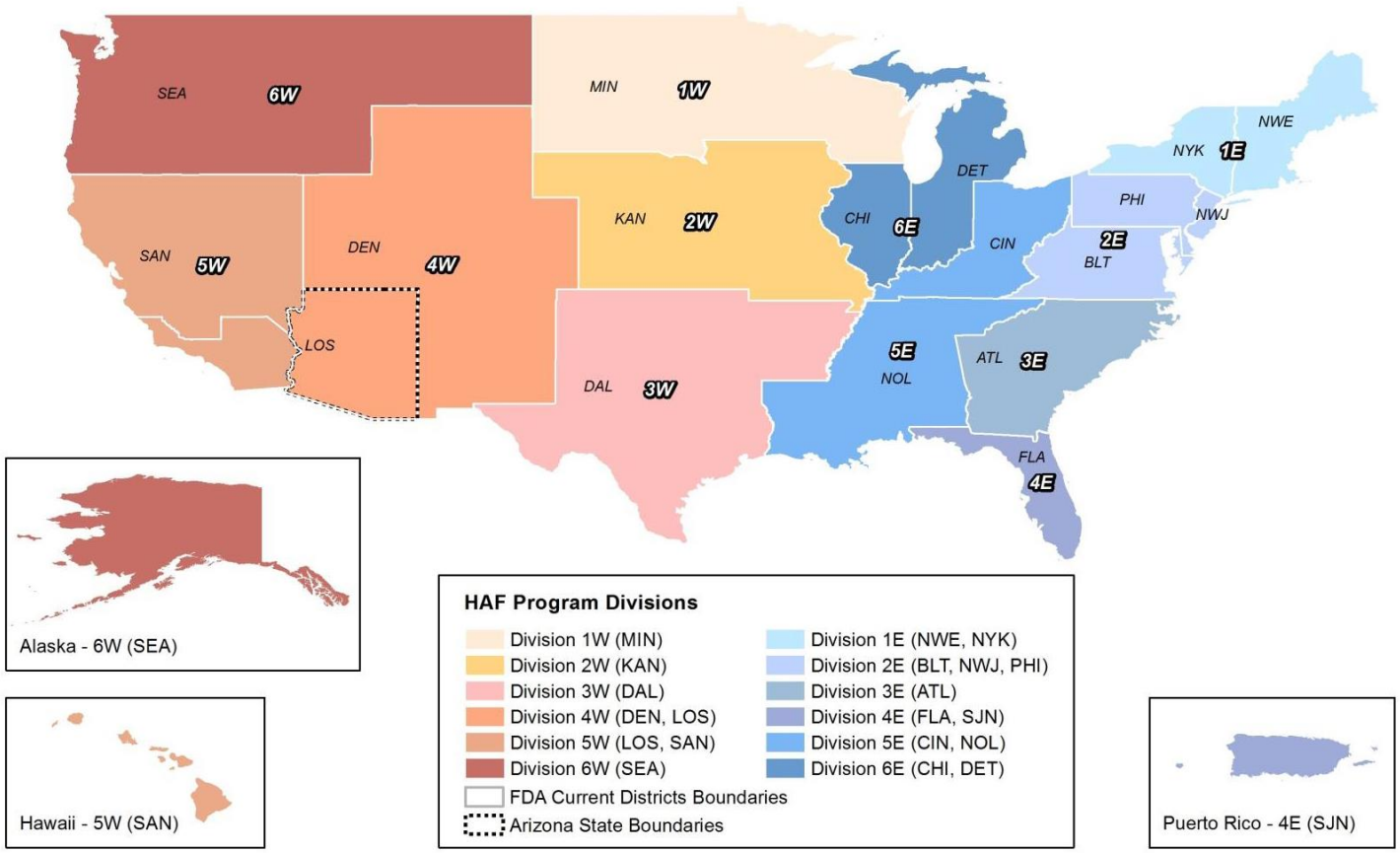
Office of Pharmaceutical Quality Operations



Office of Human and Animal Food Operations



Office of Human and Animal Food Operations



ORA Ombudsman

Jessica Zeller, JD, MA
Ombudsman

- Informally and impartially addresses concerns, complaints, and disputes between ORA and external parties:
  - Industry
  - Federal, state, territory, and tribal government entities
  - Public
- Contact:
  - 513-679-2777 or 240-535-6021
  - ORAOmbudsman@fda.hhs.gov

PUBLIC HEALTH PARTNERSHIPS:

Enhancing ORA operations by serving as an objective, neutral resource to improve communication channels, resolve disputes, and foster positive relationships with internal and external stakeholders.

Student Volunteer Service Program (SVSP)

The SVSP is one of several Federal Internships available in the Federal Government. Participants in the SVSP are unpaid volunteers.

This program is for students who are currently enrolled in an accredited educational institution seeking unpaid work experience or education-related training opportunities. Federal employee relatives may participate in SVSP consistent with the FDA policy on employment of relatives.

Volunteering at the FDA is limited to services performed by a student, with the permission of the educational institution where the student is enrolled. A written agreement between FDA and the educational institution must be established before we assign our volunteers.

https://www.fda.gov/aboutfda/workingatfda/fellowshipinternshipgraduatefacultyprograms/ucm530314.htm

In closing…

Between the FDA, Academia, Industry, National, International, Professional and Interest Group partners …

… We do our best work when we work together!


Thank you for the opportunity to speak to you today!


FDA
U.S. FOOD & DRUG
ADMINISTRATION