FDA Office of Import Operations

October 2024

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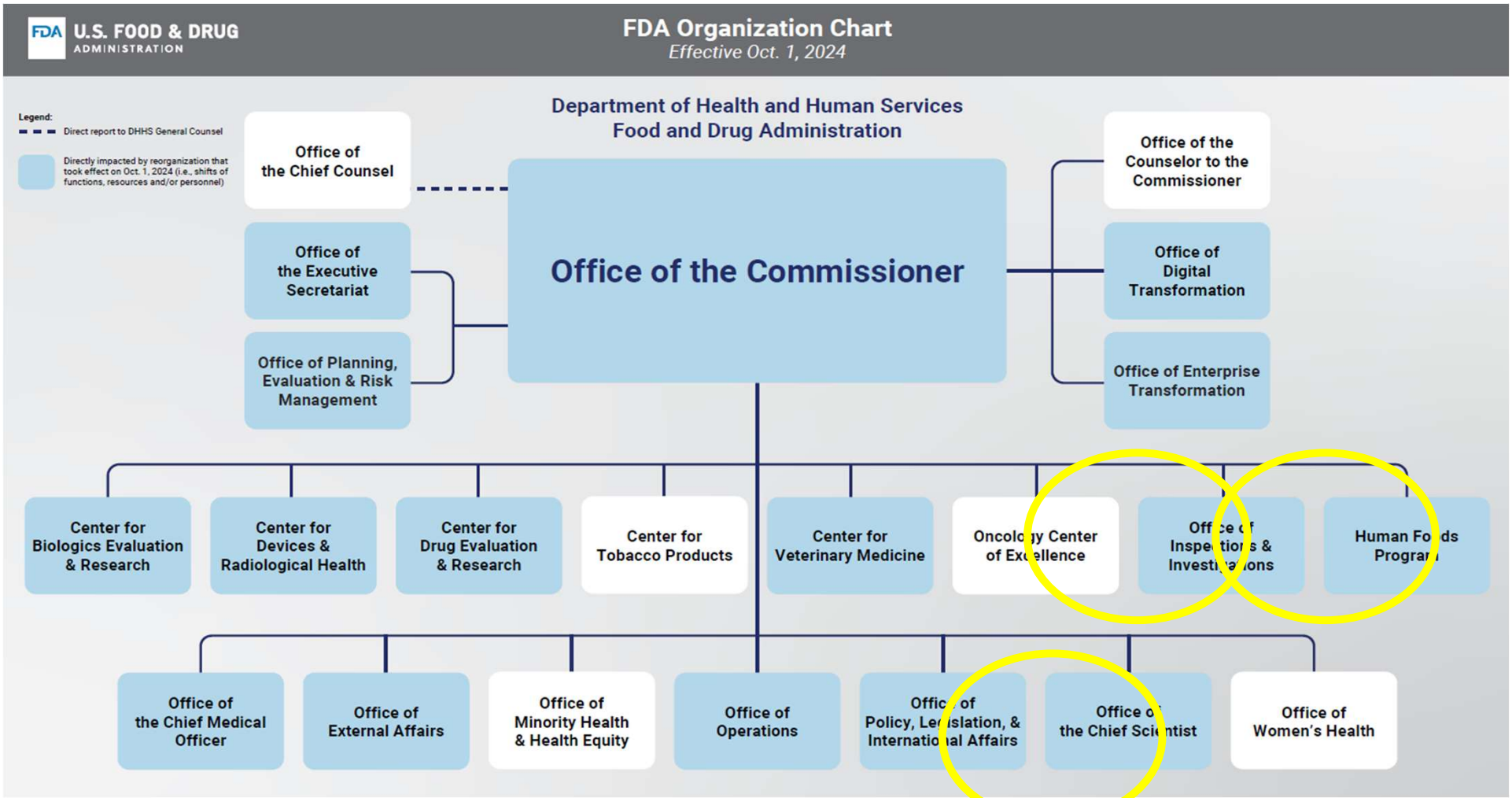
Assistant Commissioner for Import Operations

PGA Panel Part 2 (AMS Organics & FDA)

Agenda

- Introductions and Org Structure of FDA
  - Re-organization standup in FDA
  - Human Food Program
  - Office of Inspections and Investigations
- Impact to Filers
- FSVP and VQIP Updates
- Where to go for resources and information
- Questions


U.S. FOOD & DRUG ADMINISTRATION
FDA Organization Chart
Effective Oct. 1, 2024
Legend:
Direct report to DHHS General Counsel
Directly impacted by reorganization that took effect on Oct. 1, 2024 (i.e., shifts of functions, resources and/or personnel)
Department of Health and Human Services
Food and Drug Administration
Office of the Chief Counsel
Office of the Executive Secretariat
Office of Planning, Evaluation & Risk Management
Office of the Commissioner
Office of the Counselor to the Commissioner
Office of Digital Transformation
Office of Enterprise Transformation
Center for Biologics Evaluation & Research
Center for Devices & Radiological Health
Center for Drug Evaluation & Research
Center for Tobacco Products
Center for Veterinary Medicine
Oncology Center of Excellence
Office of Inspections & Investigations
Human Foods Program
Office of the Chief Medical Officer
Office of External Affairs
Office of Minority Health & Health Equity
Office of Operations
Office of Policy, Legislation, & International Affairs
Office of the Chief Scientist
Office of Women's Health

Updates- FDA

U.S. FOOD & DRUG ADMINISTRATION

FDA Organization Chart – Office of Inspections and Investigations (OII)

Effective Oct. 1, 2024

Legend:

Directly impacted by reorganization that took effect on Oct. 1, 2024 (i.e., shifts of functions, resources and/or personnel)

Department of Health And Human Services
Food and Drug Administration
Office of Inspections and Investigations

Associate Commissioner for Inspections and Investigations

Office of Field Operations & Response
Organizational Quality Staff

Office of Emergency Response
Office of Field Regulatory Operations†

Office of Business Informatics & Solutions Management

Division of Regulatory Business Informatics & Solutions
Division of Import Business Informatics & Solutions
Division of Solutions Planning, Management & Governance
Division of Work Planning & Analytics

Office of Training Education & Development

Division of Instructional Systems & Technology
Division of Multi-Program, Leadership & Management Training
Division of Programmatic Training

Office of Import Operations

Division of Targeting & Analysis
Division of Import Operations
Division of Analysis and Program Evaluation
Division of Southwest Imports
Division of Planning & Public Response
Division of Southeast Imports
Division of Northeast Imports
Division of Northern Border Imports
Division of West Coast Imports

Office of Criminal Investigations

Chicago Field Office
Metro-Washington Field Office
New York Field Office
Los Angeles Field Office
Miami Field Office
Kansas City Field Office

Office of Management

Office of Budget, Facilities & Travel Support
Office of Workforce Management

Office of Bioresearch Monitoring Inspectorate

Division of Bioresearch Monitoring Inspectorate (I-IV)
Division of Bioresearch Monitoring Global Operations

Office of Biologics Inspectorate
Biologics Global Operations Staff

Division of Biologics Inspectorate (I-III)
Division of Biotechnology Inspectorate

Office of Medical Devices & Radiological Health Inspectorate

Division of Medical Device & Radiological Health Inspectorate (I-IV)
Division of Mammography & Radiological Health Inspectorate
Division of Medical Device & Radiological Health Global Operations

Office of Human & Animal Drug Inspectorate

Division of Human & Animal Drug Inspectorate (I-VI)
Division of Human & Animal Drug Foreign Inspectorate
Division of Human & Animal Drug Global Operations

Office of Animal Food Inspectorate

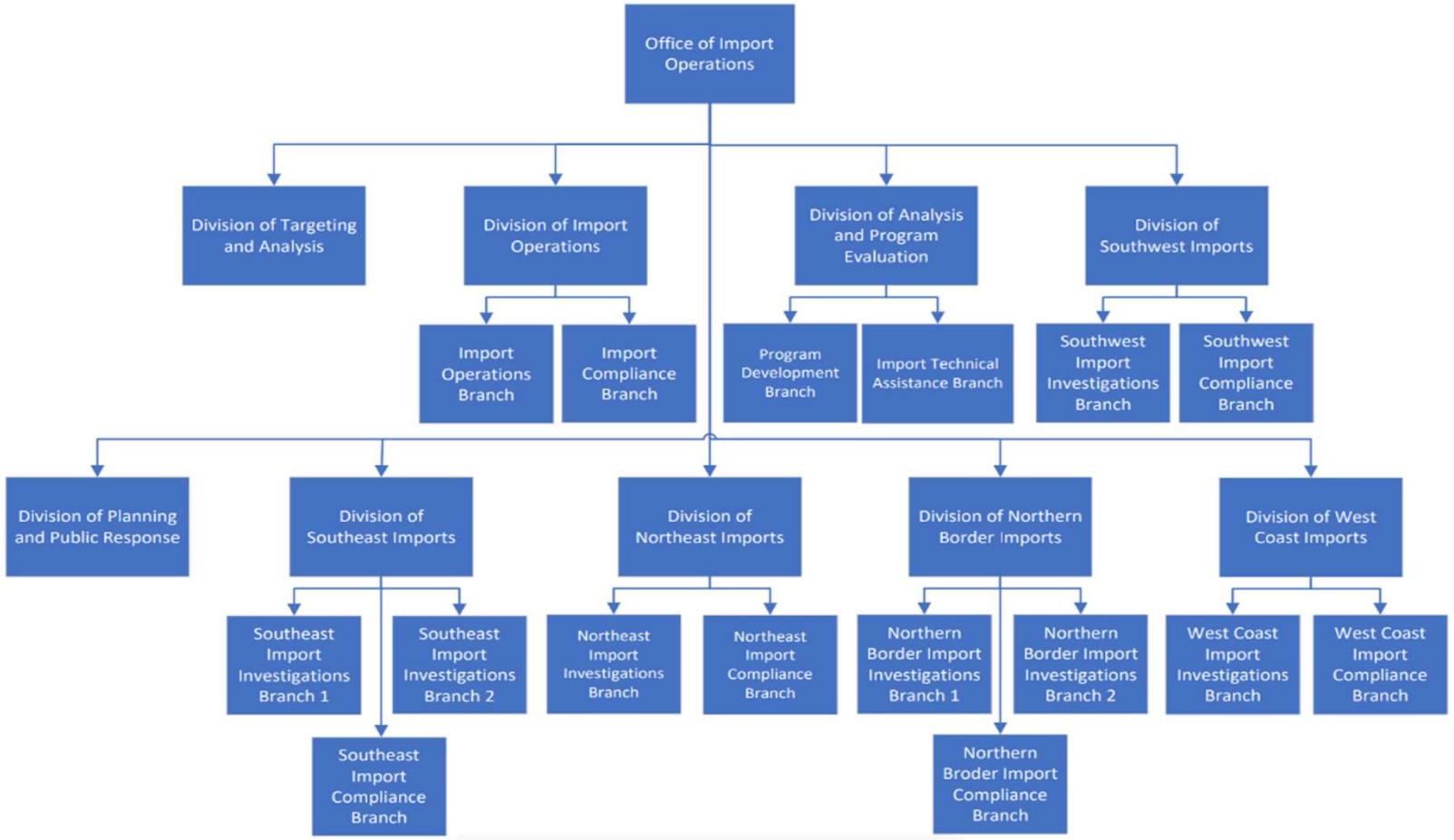
Division of Animal Food Inspectorate (I-II)

Office of Human Food Inspectorate‡

Office of Human Food East Inspectorate
Office of Human Food Central Inspectorate
Office of Human Food West Inspectorate
Office of Global & Specialty Human Food Inspectorate

†*Includes Division of Tobacco Inspectorate*
‡*Includes specialized teams for products such as infant formula*

Updates:
Office of Import Operations (OIO)



DIVISION OF TARGETING AND ANALYSIS

Harnessing intelligence, advanced technology, and comprehensive risk analytics to target import shipments of FDA regulated commodities which pose a threat to the health, safety, and security of the American public.

Data Analysis and Intelligence Research for risk-informed decision-making.

Receives and reviews Prior Notice and intelligence data

Develop methods for threat analysis, workplanning and resource allocation.

Recommends compliance actions for violations Prior Notice regulation.

Supply Chain Analysis

A liaison to Law Enforcement Agencies for the FDA.

FDA Re-Organization

What does this mean to you as a Customs Broker?

- Pay attention to any annual renewal deadlines such as Food Firm Registration
  - Deadline dates may change
  - The office name may change including email address but the contact phone numbers should not change
  - Use this link for current updates: FDA Modernization Efforts for Establishing a Unified Human Foods Program, New Model for Field Operations and More | FDA
- No Food Centers, now Human Food Program
- Office of Cosmetics is now with Office of Chief Science
- Food Laboratories are now under HFP
- Medical Products Laboratories are now under Office of Chief Science
- FSMA Regulations such as FSVP and VQIP Programs will be refocused area of improvements
- Lab results will be coming from different offices now and not your local FDA Office.

FSVP, Who Must Comply?

- "Importer" is US owner or consignee of a food at time of US entry (defined as person in US who, at time of entry, owns the food, has purchased it, or has agreed in writing to purchase it)
- If no US owner or consignee at entry, importer is US agent or representative of foreign owner or consignee
  - Signed statement of consent required

Voluntary Qualified Importer Program(VQIP)

- Part of FSMA
- For importers of human and animal food
- Voluntary, fee-based
- Expedited review and entry of imports for approved applicants

- Products Included
  - Any FDA-regulated human and/or animal food, as defined in the FD&C Act, ***including but not limited*** to:
    - Seafood
    - Produce
    - Processed foods
    - Dietary supplements
    - Pet food

How do *importers* apply for VQIP?

- Importers will be able to apply to the VQIP Program online at the **FDA Industry Systems website** beginning January 1 through May 31st of each calendar year.

- An account will need to be established and a **Notice of Intent to Participate** in VQIP must be submitted before submitting an application.

- The **VQIP Portal User Guide** covers step by step instructions for applying for VQIP.

- The **VQIP Guidance for Industry** describes FDA's policy regarding participation VQIP by importers of food for humans or animals.

Questions?

Resources

- **Import Program – Food and Drug Administration (FDA)**

This link will take you to the FDA Import Program home page. You will be able to navigate to all FDA Import Resources from this page.

- **Import Systems**

This link will discuss the various import systems that are used.

- **Import Trade Auxiliary Communication System (ITACS)**

This link will take you to the ITACS information page. ITACS basic functionality provides the import trade community the ability to electronically: check the status of FDA-regulated entries and lines, submit entry documentation, submit the location of goods availability for those lines targeted for examination by the FDA, and check the estimated laboratory analysis completion dates for lines which have been sampled. An Importer of record can have an ITACS account.

- **Automated Commercial Environment/International Trade Data System (ACE/ITDS)**

There are associated links on this page that discuss technical requirements for filing an entry. This information can be helpful to everyone. For example, if a data element is required to be transmitted via ACE, an Importer of Record will want to provide this information to the entry filer.

Contact the FDA Import Program

The FDA's Office of Import Operations (OIO) is the lead office for the FDA's Import Program.

- **FDA Import Offices and Ports of Entry**
  - Entry-related and/or entry status inquiries
  - **Courier Coverage Information**
    - Entry-related and/or entry status inquiries for courier ports of ent
- **Division of Food Defense Targeting (Prior Notice)**
  - Prior Notice related inquiries, including filing, policy, status, etc.
- **Division of Import Operations**
  - General import operational and policy questions:
    - Phone: (301) 796-0356
    - Email: FDAImportsInquiry@fda.hhs.gov
  - Petitions for removal from Detention without Physical Examination (i.e., Import Alert):
    - Email: ImportAlerts2@fda.hhs.gov
- **ACE Technical Support**
  - FDA-related ACE questions:
    - Email: ACE_Support@fda.hhs.gov