

FDA Office of Import Operations

March 2024

Dan Solis, FDA
Assistant Commissioner for Import Operations

Jeff Brown, FDA
Consumer Safety Officer

Kathleen Turner, D.V. M., FDA
Program Division Director for the Division of West Coast Imports

Agenda

- Introductions and Structure of OIO (Dan Solis)
  - FDA Imports and Contacts
  - Upcoming Re-organization in FDA
- FDA's Pacific Island Project (Dan Solis)
  - Updates and Public Health Impact (Jeff Brown)
  - Next Steps
- Division of West Coast Imports (Dr. Kathleen Turner)
  - Overview
  - Partnership Agreements
  - Pacific Island Activities
- Questions





Dan Solis
Assistant Commissioner for Import Operations



John Verbeten
Deputy Director for Import Operations Enforcement



Faiad Rahaman, Ph.D.
Deputy Director for Targeting, Analysis, and Support



Todd Cato
Program Division Director DSWI



Keith Jasukaitis
Program Division Director DNBI



Samantha McCormick
Acting Director Division for Food Defense Targeting



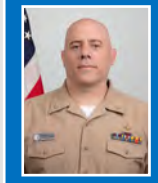
Alison Nicoli
Director for Import Operations



Kathleen Turner, DVM
Program Division Director DWCI



Ruth Dixon
Program Division Director DSEI



CDR Joseph Tomao
Program Division Director DNEI

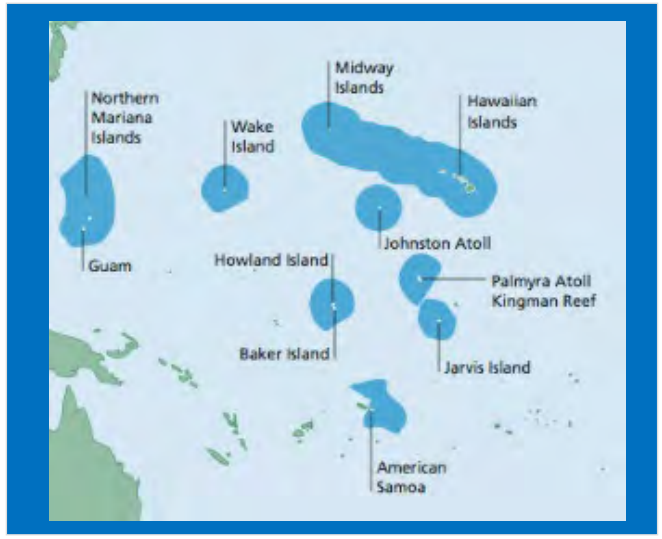
Office of Import Operations (OIO) Senior Leadership Team

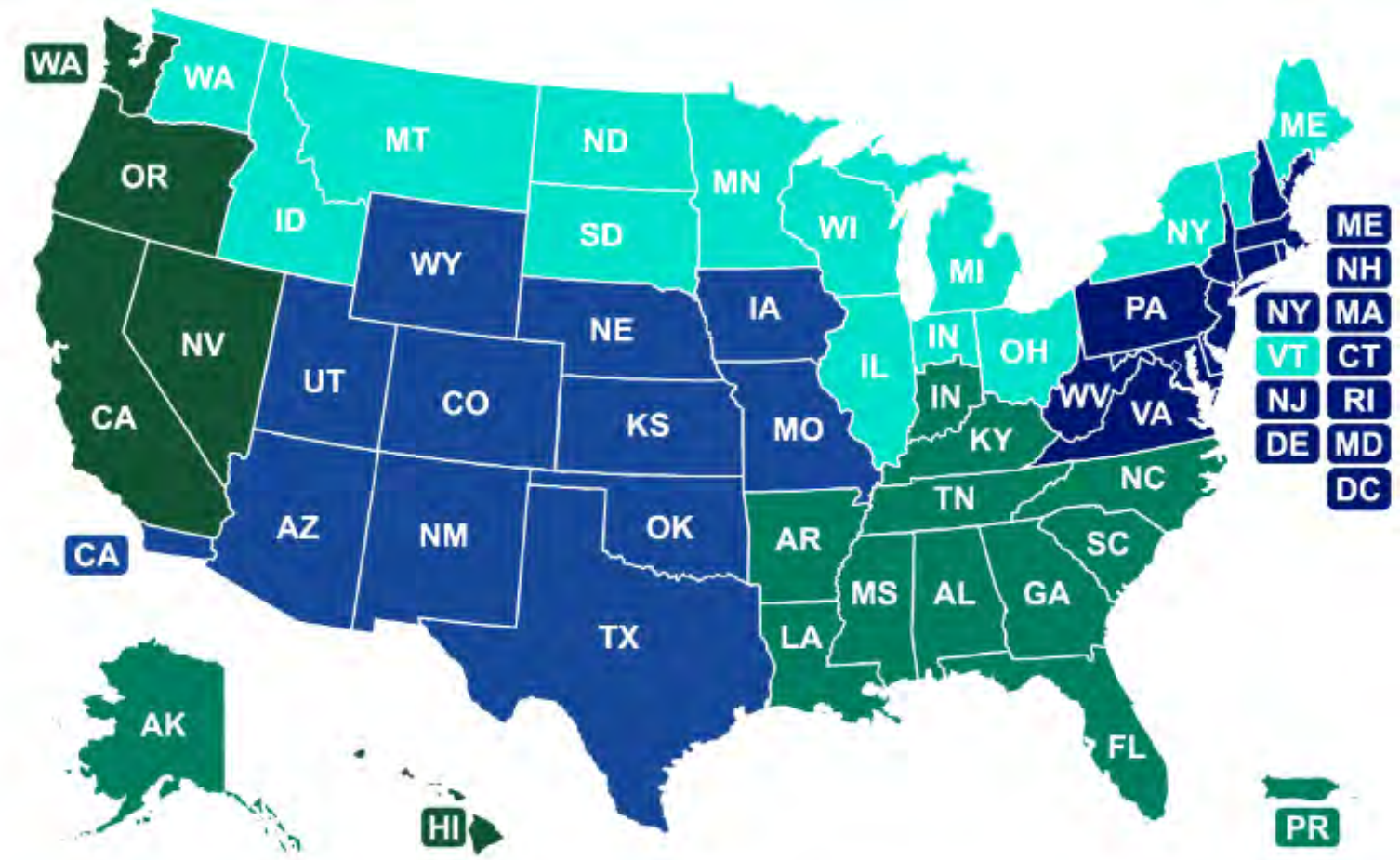
FDA Import Offices and Ports of Entry

Import Divisions

7 Import Divisions

- 5 Field Divisions
  - Division of West Coast Imports (DWCI)
  - Division of Southeast Imports (DSEI)
  - Division of Northern Border Imports (DNBI)
  - Division of Northeast Imports (DNEI)
  - Division of Southwest Imports (DSWI)
- 2 Headquarter Divisions
  - Division of Import Operations
  - Division of Food Defense Targeting





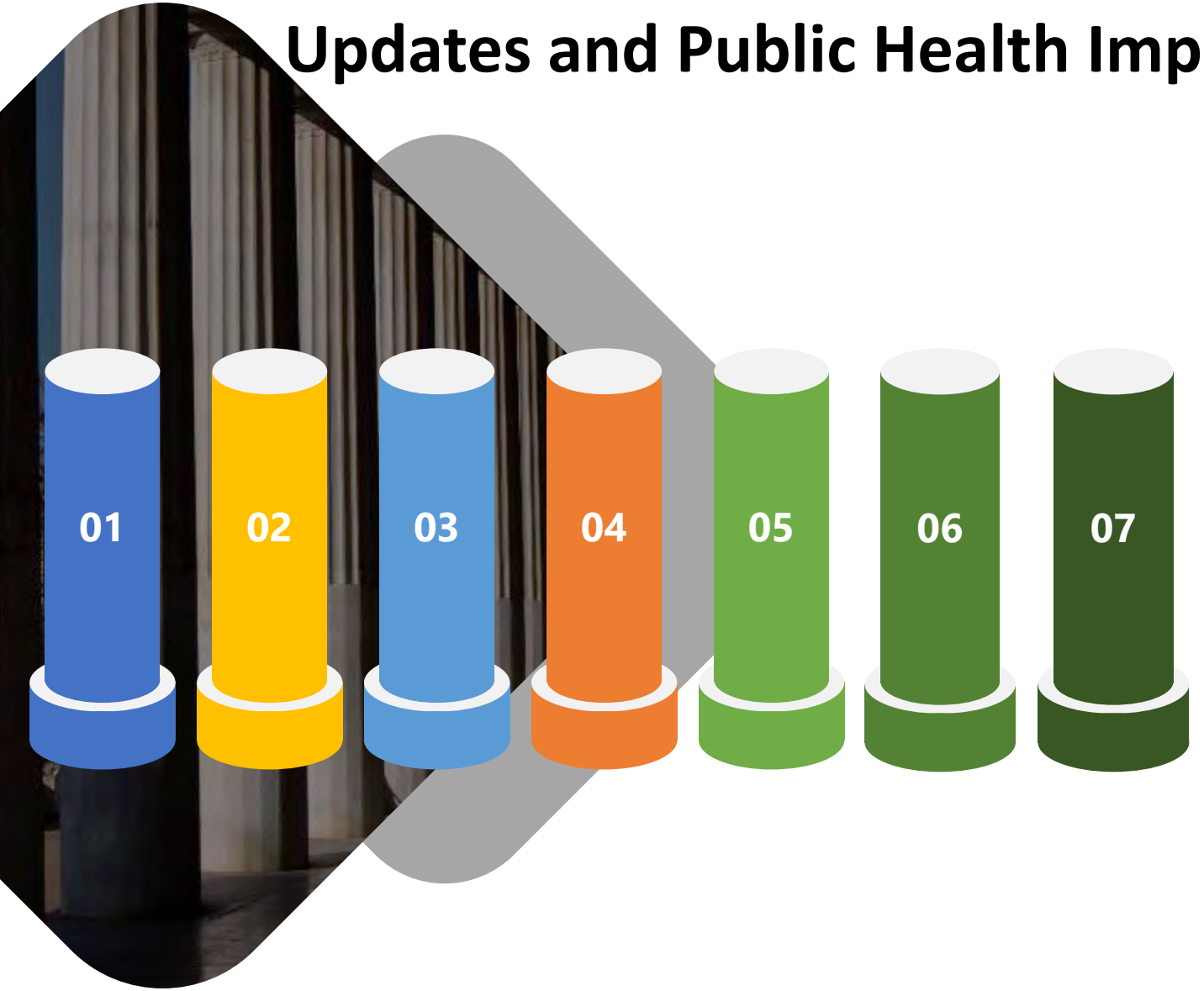
The Future of FDA

Upcoming Re-Organization

Vision: An Integrated ORA Supporting the Entire FDA Portfolio



FDA OIO's Pacific Island Program Updates and Public Health Impact



FY24 Strategic Pillars

Pillar 1: Enhance Regulatory Oversight
Strengthen and modernize regulatory frameworks to ensure the safety, efficacy, and drugs, medical devices, and other products within Guam US Territory.

Pillar 2: Improve Inspection & Enforcement
Increase the frequency and effectiveness of inspections and enforcement actions to identify and address non-compliance issues promptly, ensuring that businesses (importers and consignees) adhere to FDA regulations.

Pillar 3: Capacity Building and Training
Invest in training programs and capacity-building initiatives for FDA staff and local stakeholders to enhance regulatory knowledge, inspection capabilities, and overall competence in drugs, and medical devices regulatory compliance.

Pillar 4: Collaboration w/ Island Authorities
Strengthen partnerships with Guam's regulatory agencies (DPHSS, CQA, AG Office, Other Island Partners) to share best practices, exchange information, and coordinate efforts for a more effective and harmonized regulatory framework.

Pillar 5: Digital Transformation
Embrace technology to modernize regulatory processes, data management, and communication, improving efficiency, transparency, and the ability to respond rapidly to emerging challenges.

Pillar 6: Community Engagement and Education
Develop and implement outreach programs to engage with the local community, providing information about FDA regulations, promoting consumer awareness, and fostering a collaborative approach to public health.

Pillar 7: Emergency Preparedness and Response
Increase coordination of emergency response and preparedness activities; including outbreak investigations, injury and illness complaints or reports of tampering, national emergencies, as well as natural and man-made disasters that involve FDA-regulated products and FDA regulated industries.

Guam Regional Office Project Dashboard

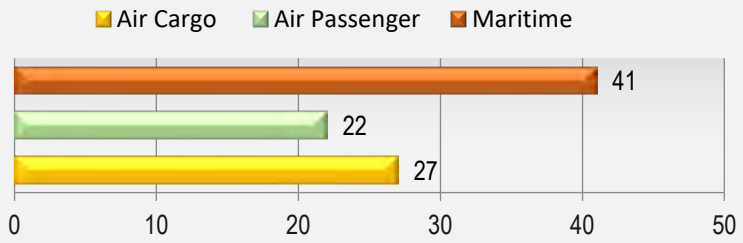
PROGRAM OBJECTIVES

Protect U.S. citizens; improve intelligence of imported goods entering the U.S. mainland, Hawaii, and U.S. Territories; build sustainable regulatory capacity and capability for Guam and the Pacific Islands; provide a conduit for FDA laboratory engagement to support the analysis of imported products; inform Office of Criminal Investigations operations through direct engagement in the Pacific Region; and broaden FDA's international presence and engagement.

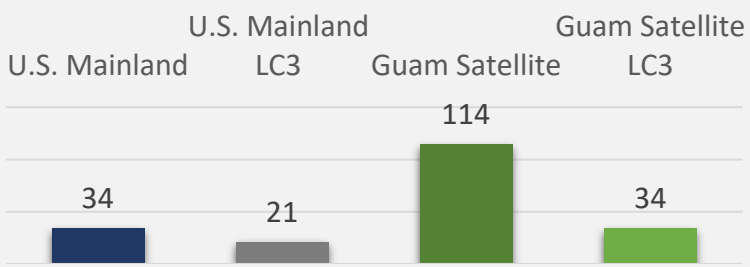
STRATEGIC PILLARS

Pillar 1: Enhance Regulatory Oversight
Pillar 2: Improve Inspection & Enforcement
Pillar 3: Capacity Building and Training
Pillar 4: Collaboration w/ Guam Authorities
Pillar 5: Digital Transformation
Pillar 6: Community Engagement and Education
Pillar 7: Emergency Preparedness and Response

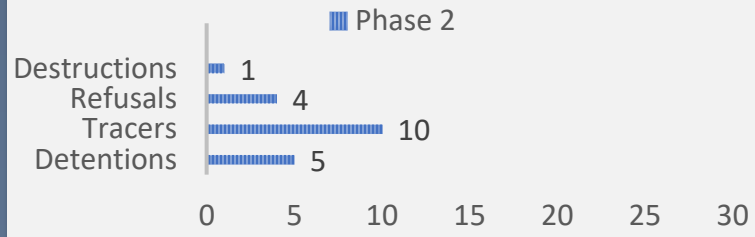
EXAMINATIONS



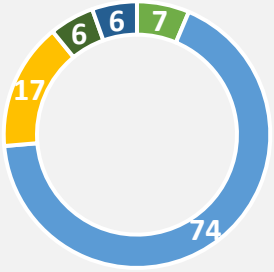
LABORATORY SAMPLES

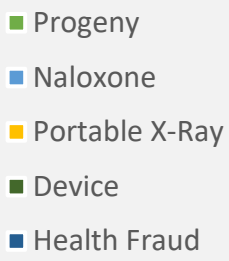


Actions from FDA Recommendations



REGULATORY TRAINING





Training of FDA Staff and External Regulatory Partners

UNDERCOVER BUYS

150

Drugs, Dietary Supplements, and Food Products

FIELD INVESTIGATIONS & MARKET SURVEILLANCE ACTIVITIES

15

*Data received from Detailees on island spans from the Guam Pilot 2022 to Q2 of 2024.

FDA OIO's Pacific Island Program

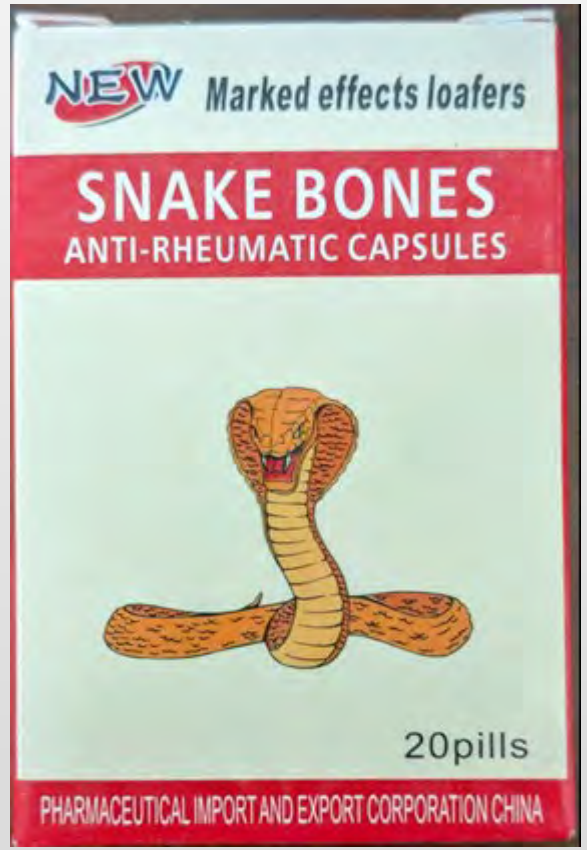
Updates and Public Health Impact



[2-29-2024] The Food and Drug Administration is advising consumers not to purchase or use QUICK Rheumatism Capsule, Tiger Wang Biaod, a product promoted and sold for rheumatism on various websites and possibly in some retail stores...

[QUICK Rheumatism Capsule, Tiger Wang Biaod contains hidden drug ingredient | FDA]

[2-29-2024] The Food and Drug Administration is advising consumers not to purchase or use SNAKE BONES Anti-Rheumatic Capsules, a product promoted and sold for rheumatism on various websites and possibly in some retail stores...



[SNAKE BONES Anti-Rheumatic Capsules contains hidden drug ingredient | FDA]

FDA OIO's Pacific Island Program Updates and Public Health Impact



Medication Health Fraud Questions and Answers

Search a database of more than 1,000 unapproved products and learn about medication health fraud and red flags



Products with Hidden Ingredients

FDA testing identified products promoted for sexual enhancement, weight loss, body building, arthritis/pain, or use as sleep aid that contain hidden drug ingredients



Counterfeit Medicines

Illicit, counterfeit medicine is fake and may be harmful to your health

https://www.fda.gov/drugs/buying-using-medicine-safely/medication-health-fraud

FDA OIO's Pacific Island Program Moving Forward

Detailees

Permanent Supervisor

Permanent Employees



U.S. FOOD & DRUG ADMINISTRATION

FDA
Office of Import Operations
Division of West Coast Imports

Dr. Kathleen Turner, DVM
Program Division Director





- DWCI Overview
- Partnership Agreements
- Pacific Island Activities



Division of West Coast Imports

Washington, Oregon, Nevada, California, Hawaii, and the U.S. Pacific Territories

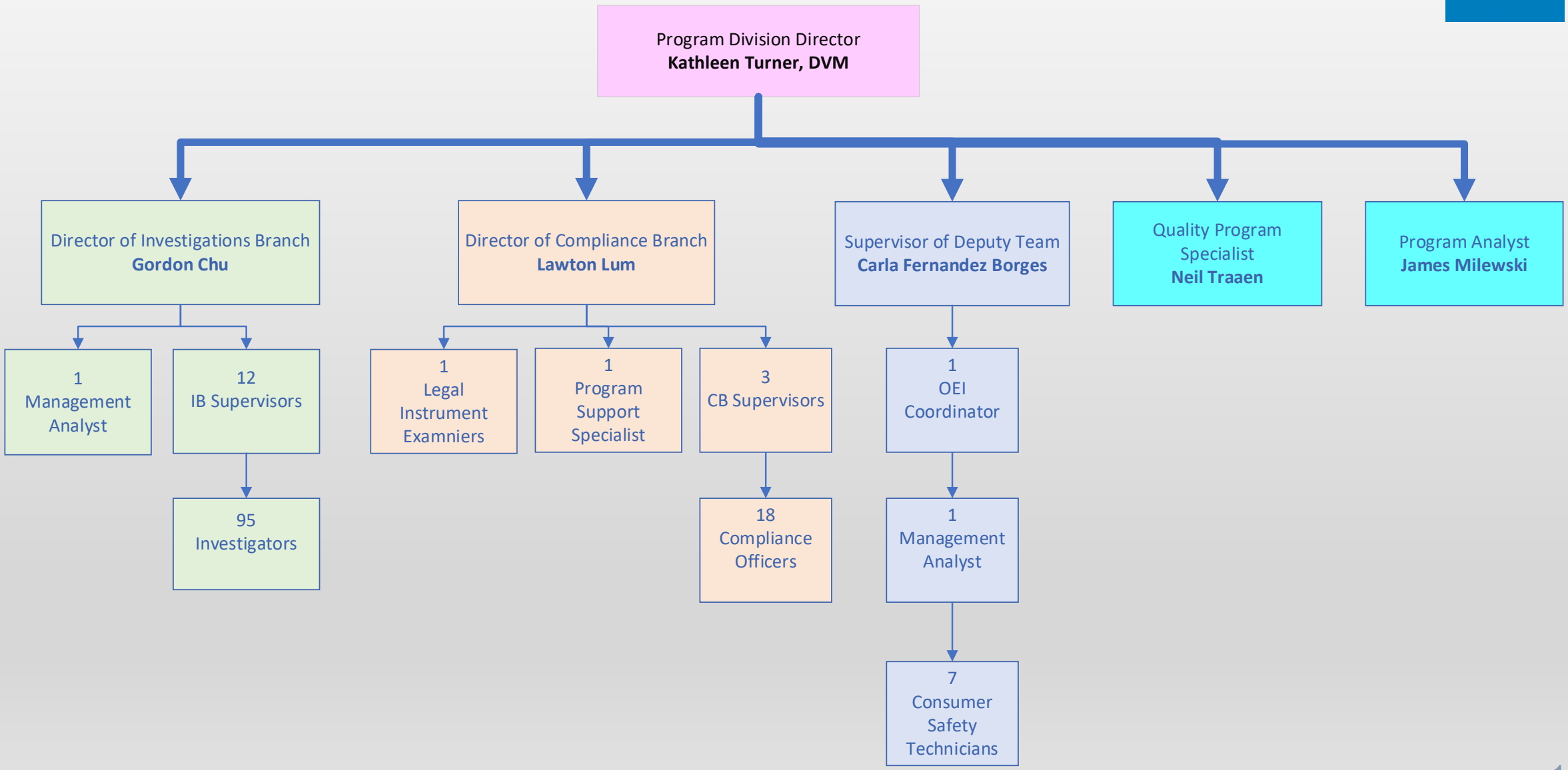
Airports

Seaports

Centralized Examination Stations (CES)

International Mail Facilities (IMF)

Division of West Coast Imports



Partnership Agreements



Partnership Agreement Between U.S. Food and Drug Administration, University of Hawaii, and the State of Hawaii by its Departments of Agriculture and Health

Pacific Island Activities

Operations

Outreach

Operations





IMF
(International Mail Facility)

- National Operational Strategy (NOS) for Operation Guam
- Operation Palm Tree



MASFO

DWCI

American Samoa

Guam

Honolulu

Saipan








COMMONWEALTH HEALTHCARE CORP.
Established October 2011
COMMONWEALTH OF THE NORTHERN MARIANAS


Protecting and Promoting Your Health
FDA U.S. FOOD & DRUG ADMINISTRATION



Outreach

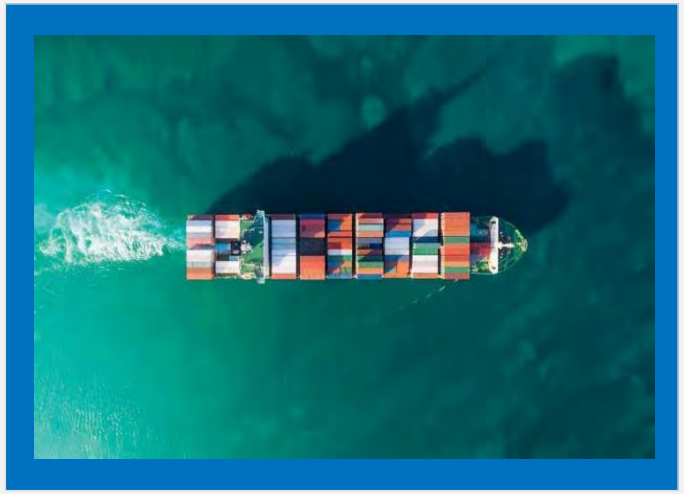
New Honolulu Imports Office



FDA OIO's Pacific Island Program

Thank You!





FDA OIO's Vision

- Public health protection for US. Citizens, including those located on U.S. territories in the pacific islands
- Expanded public health protection for the United States

Importance of Partnership

- A program this large, and with this much impact for the U.S. and U.S. territories, cannot be stood up or executed without the work of many agencies



Questions





Thank you!

FDA U.S. FOOD & DRUG ADMINISTRATION



