

FDA
Office of Enforcement and
Import Operations
*Division of West Coast
Imports*



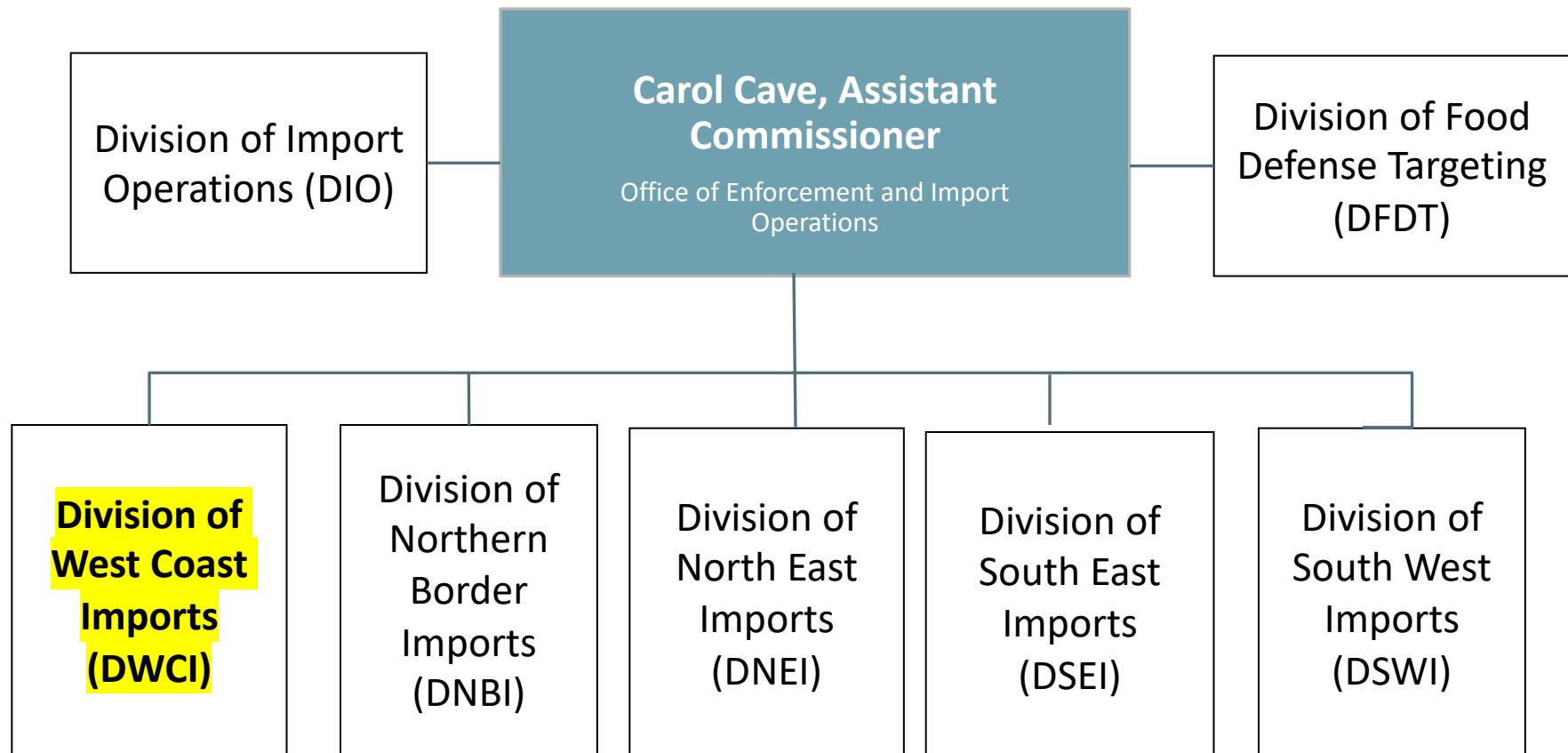
***Pacific Island Health
Officers Association
Meeting***

Honolulu, HI

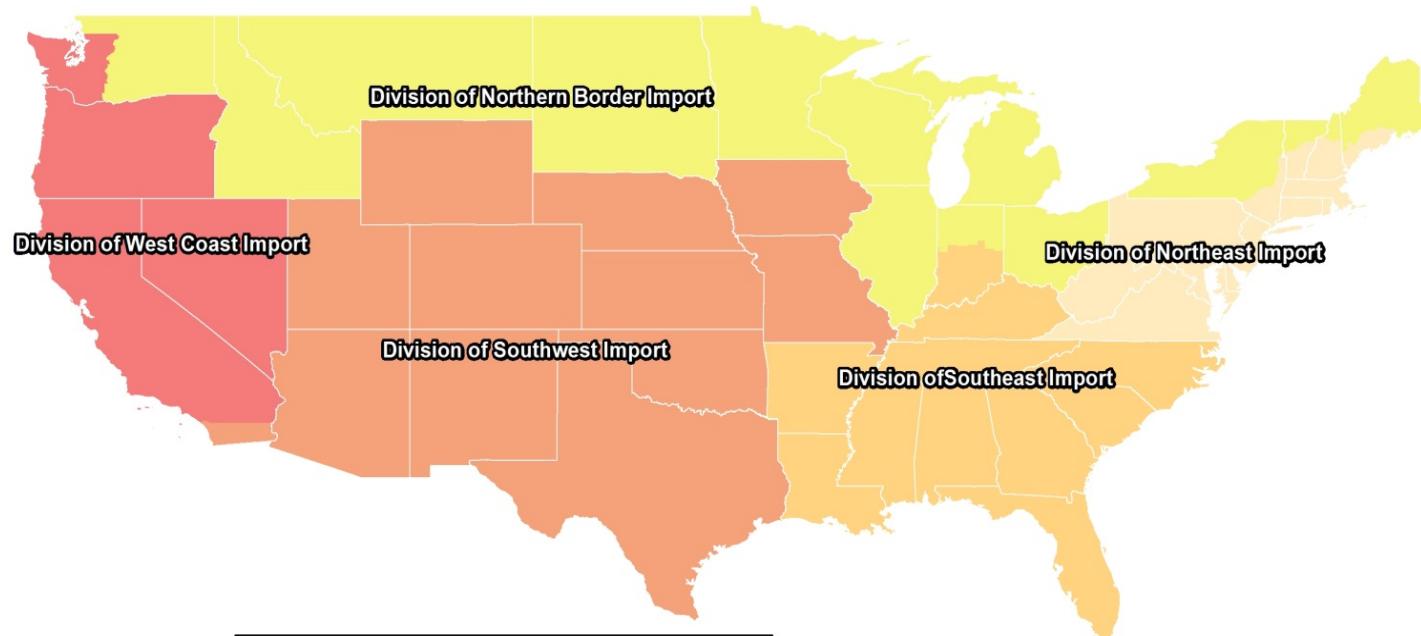
November 21, 2019

Dan Solis, Division Director
Gordon Chu, Director of Investigations Branch
Timothy Mueller, Director, Division of Integration





Office of Enforcement and Import Operations (OEIO)



Import Program Divisions

- Division of Northeast Import (CT, DC, DE, MA, MD, ME, NY, NH, PA, RI, VA, VT, WV)
- Division of Northern Border Import (ID, IL, IN, ME, MI, MN, MT, NH, ND, NY, OH, SD, VT, WA, WI)
- Division of Southeast Import (AK, AL, AR, FL, GA, IN, KY, LA, MS, NC, PR, SC, TN)
- Division of Southwest Import (AZ, CO, IA, KS, MO, NE, NM, OK, TX, UT, WY)
- Division of West Coast Import (CA, HI, NV, OR, WA)
- State Boundaries





Division of West Coast Imports



MAIN IMPORT OPERATIONS OFFICE – Long Beach, CA



Airports

Seaports

CENTRALIZED EXAMINATION STATIONS (CES)

International Mail Facility (IMF)



States of:

- **Washington** (Tacoma, Seattle)
- **Oregon** (Rose City)
- **Nevada** (Las Vegas)
- **California** (Offices in Stockton, Alameda, South San Francisco, Woodland Hills, El Segundo, Long Beach, Carson, Torrance, Ontario, San Diego)
- **Hawaii** (Honolulu)

FDA Responsibilities



- Other than Food, Drugs and Medical Devices what other commodities does FDA regulate?
 - Seafood Safety
 - Vaccines
 - Cosmetics
 - Contact lenses
 - Sunglasses
 - Radiation emitting devices
 - Dietary Supplements
 - Emerging ...
 - Vaping Products
 - CBD in food
 - Whitening Creams
 - Unapproved Opioid Products
 - Fake medicine

IMPORT PROGRAM PRIORITIES



- Prescription opioids and unapproved drugs coming in through air and mail
- Vaping Products
- Food Importer inspections and supply chain investigations – FSVP
- Seafood Interdictions and Dietary Supplements Interdiction efforts at the ports
- Supply chain investigations
- Joint operations with CBP and PGA

OEIO Supports DWCI Efforts in the

Pacific

- Started in 2017 - Pacific Island Monthly Meeting (PIMM). The purpose of the meeting is to provide a forum for the Pacific Islands, to discuss about emerging public health issues, addressing Pacific Island needs, and leveraging technical knowledge and expertise from one another.
- July 15-19, 2019: Saipan (CNMI) Training
- July 1, 2019: 20.88 Agreement discussion with CNMI
- In June of 2019 the FDA started writing a Partnership Agreement between the FDA's Division of West Coast Imports (DWCI) and the Pacific Island Health Officer Association (PIHOA).
- November 6-13, 2019 = Joint Ops called Multi-Agency Strike Force Operation (MASFO) in Saipan. Training was provided to CNMI Customs Officers and representatives from the Commonwealth Healthcare Corporation Bureau of Environmental Health (CHCC-BEH), CNMI Attorney General's Office, the U.S. Coast Guard, and other CNMI regulatory personnel. DWCI FDA Investigator also helped out with container examination and interdiction activities.

Partnership Agreement with PIHOA

- In June of 2019 the FDA started writing a Partnership Agreement between the FDA's Division of West Coast Imports (DWCI) and the Pacific Island Health Officer Association (PIHOA). A Partnership Agreement (PA) acts as a foundation for support, help, and provides an exchange of goods or services.

Thank You For Your Attention!



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Thank you!

FDA PACIFIC ISLAND PARTNERSHIP

A YEAR IN REVIEW

2019

OUTLINE

- Pacific Island Monthly Meeting (PIMM)
- Providing Import Training
- Joint Operation (CNMI MASFO Highlights)
- 2020 Objectives

Pacific Island Monthly Meeting (PIMM)

- The purpose of the meeting is to provide a forum for the Pacific Islands, FDA, CDC, and State of Hawaii Public Health Department to discuss about emerging public health issues, addressing Pacific Island needs, and leveraging technical knowledge and expertise from one another.

The Evolution of PIMM

2017

- ORA Office of Regulatory Science (ORS)
- The Division of West Coast Imports (DWCI)
- The Pacific Island

2019

- ORS
- DWCI
- DFDT
- HAF
- OP
- OSPOP
- FDA Centers
- CDC
- State of Hawaii
- Pacific Island
- ASTHO

Highlights of Past PIMM Topics

- Presentation by DFDT. Guam and CNMI benefitted from the presentation because they got a better understanding about Prior Notice and how it relates to product being imported into their ports.
- OSPOP Division of Information Disclosure Policy to give a presentation on Information sharing and 20.88 agreements.
- CVM gave presentations on Good Aquaculture Practice and Medicated Animal Feed. The presentations helped address questions related to issue involving seafood safety and medicated feed in CNMI.

Highlights of Past PIMM Topics Cont.

- Office of Partnership gave a presentation on Partnership Agreement, Cooperative Agreement, and Conference Grant. This presentation helped facilitate the development of a Partnership Agreement with PIHOA.
- DWCI provided information to Guam related to FDA public hearing on cannabis and cannabis-derived compounds.

Provided Import Training

- **Dates:** July 15-19, 2019: Saipan (CNMI) Training
- DWCI traveled an Import Supervisor and Compliance Officer to CNMI and provide training to the Bureau of Environmental Health and other local agencies.

What Type Of Import Training?

- FDA label requirements of imported product;
- FDA import regulations related to cosmetic, drug, food, and medical devices
- FDA enforcement authority
- FDA interdiction strategy on smuggled goods
- FDA Import screening process
- FDA field exam and sampling process
- FDA import investigation techniques

Import Training Cont.

- **Outcome:** The training enhanced the knowledge of local health inspectors and representatives from local agencies related to FDA import authorities. The training also offer potential solution in addressing some of the regulation gaps in CNMI. DWCI Import Supervisor and Compliance Officer were able to network with local agencies and offer assistance in addressing future questions related to FDA regulation. The training was well-received by the attendee.

Joint Operation

- Multi Agency Strike Force Operation (MASFO) in CNMI
- Date: November 12-15, 2019
- Agencies involved: CNMI Customs, U.S. Coast Guard, DEA, HSI, FDA, and CNMI local agencies
- Objective: container examination at CNMI port by leveraging resources, authority, and knowledge in interdicting smuggled and potentially adulterated goods

MASFO

- DWCI Import Specialist and Supervisor provided FDA commodity training and examination technique to all participating agencies.
- DWCI has participated on average 5 MASFO in the U.S. West Coast per year.
- Great collaboration for all participating agencies and looking forward to expand to other Pacific Island.

2020 Objectives

- Continue PIIMM call and expand participants
- Conduct Joint Operations with other Pacific Island and strengthen our partnership
- Work toward a 20.89 Agreement (information sharing agreement) with Palau, The Marshall Island, and FSM
- Continue to provide import training to the Pacific I

