THE ALMOND CONFERENCE 2020 JOIN THE JOURNEY

NAVIGATING U.S. GOODS RETURNED: FDA INSIGHTS

Tim Birmingham, *Almond Board of California*

Gordon Chu, U.S. *Food and Drug Administration*

Lawton Lum, U.S. *Food and Drug Administration*

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Navigating U.S. Goods Returned – FDA Insights
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Today's Speakers

- Tim Birmingham
  - Director Quality Assurance and Industry Services
  - Almond Board of California

- Gordon Chu
  - Acting Program Division Director
  - Division of West Coast Imports
  - Office of Enforcement and Import Operations
  - U.S. Food and Drug Administration

- Lawton Lum
  - Director, Compliance Branch
  - Division of West Coast Imports
  - Office of Enforcement and Import Operations
  - U.S. Food and Drug Administration

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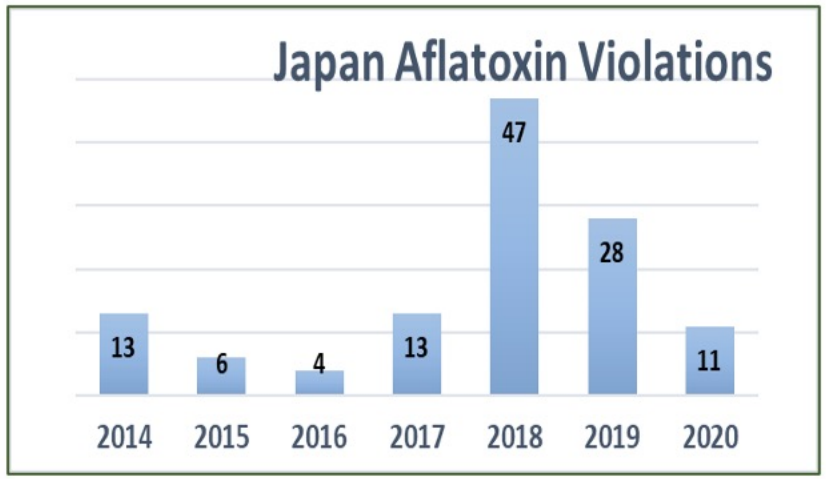
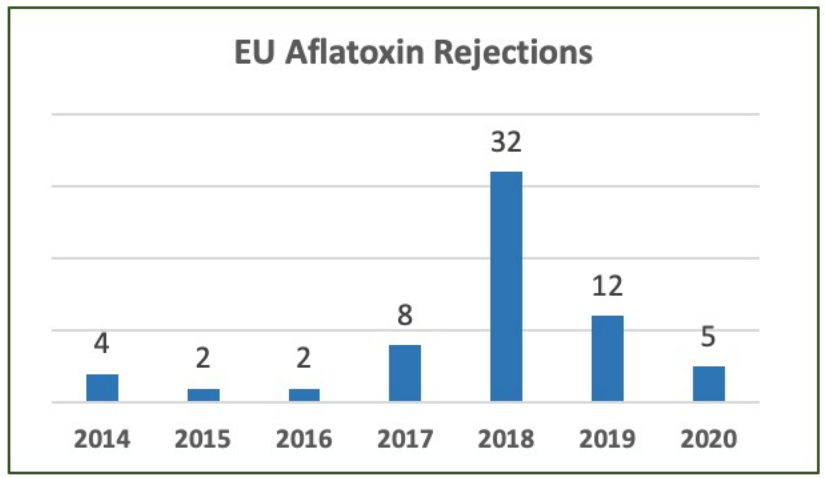
Tips for a Successful Session

- Use chat feature or Q&A feature to ask questions during the session
- Some questions may be answered via chat during the session
- Please make sure to join us in the lounge for live Q&A with Gordon and Lawton immediately after my closing remarks
- Feel free to email any questions after the session to me at tbirmingham@almonboard.com for follow up with our speakers
- A Q&A fact sheet will prepared based on questions asked & answered and will be made available to participants

Why Are We Still Talking About Goods Returned Process?





- Aflatoxin rejections have decreased over past two crop years
- We will still continue to see rejections as crop grows
- Higher insect damage years can result in further number of rejections
- Any product brought back to the U.S. must meet U.S. regulatory requirements

FDA treats all goods entering U.S. Ports as Imports – Regardless of country of origin

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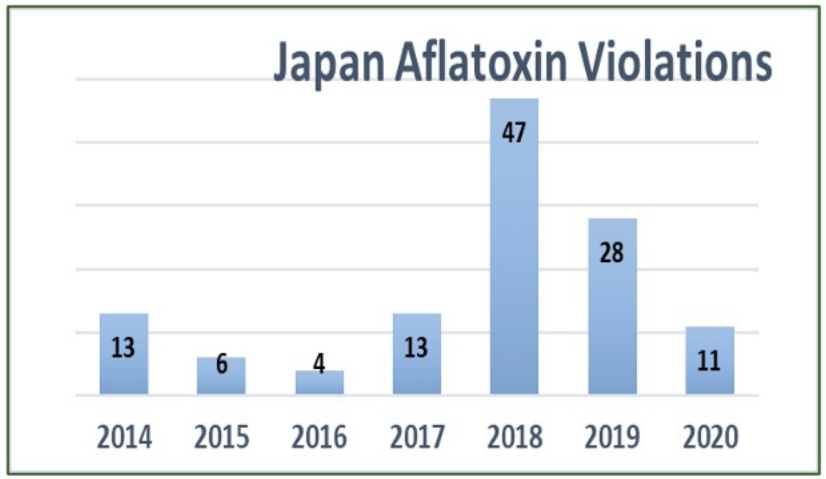

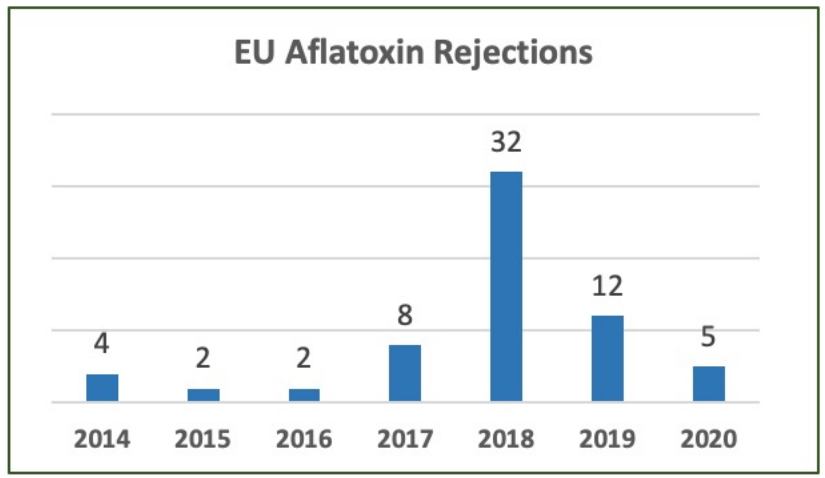

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Today's Talk – FDA Insights

- Organizational Structure
  - Role of Compliance and Investigations branches within Division of West Coast Imports
- Importation Process
- Practical Steps involved in bringing the goods back
- FDA Notifications
- Reconditioning Product
- Things to be mindful of to avoid delays or refusals

After the presentations we will be having live Q & A in the Lounge

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Gordon Chu, *U.S. Food and Drug Administration*

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Almond Board of California

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

Almond Conference

December 9, 2020

Gordon Chu, Acting Program Division Director
Lawton Lum, Director of Compliance Branch

Our Objectives

I. Introduction to the Organization

II. DWCI Structure and Operations

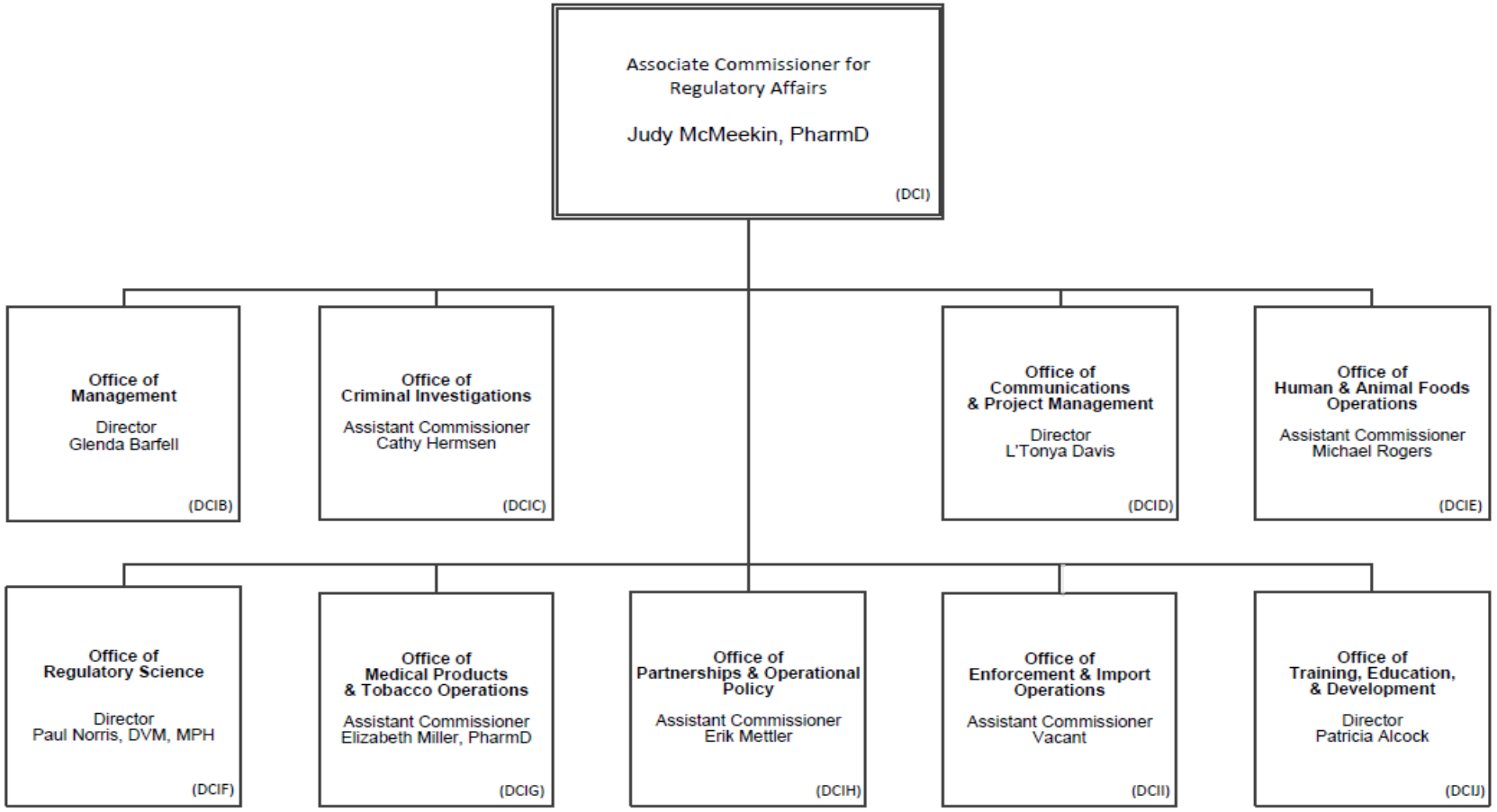
III. Actual Walk-through of the import process

IV. Compliance Review

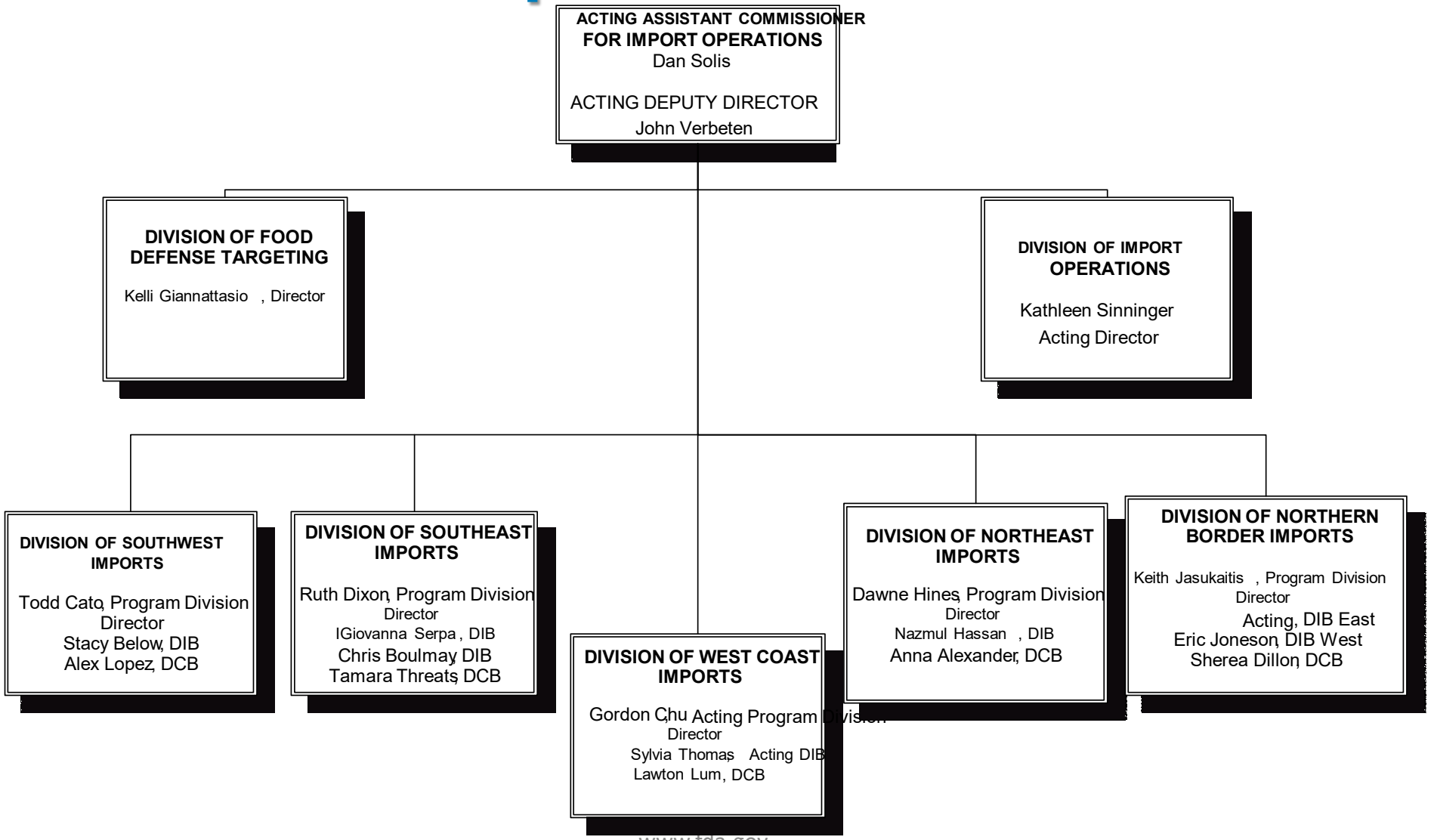
ORA Organizational Chart

September 2020

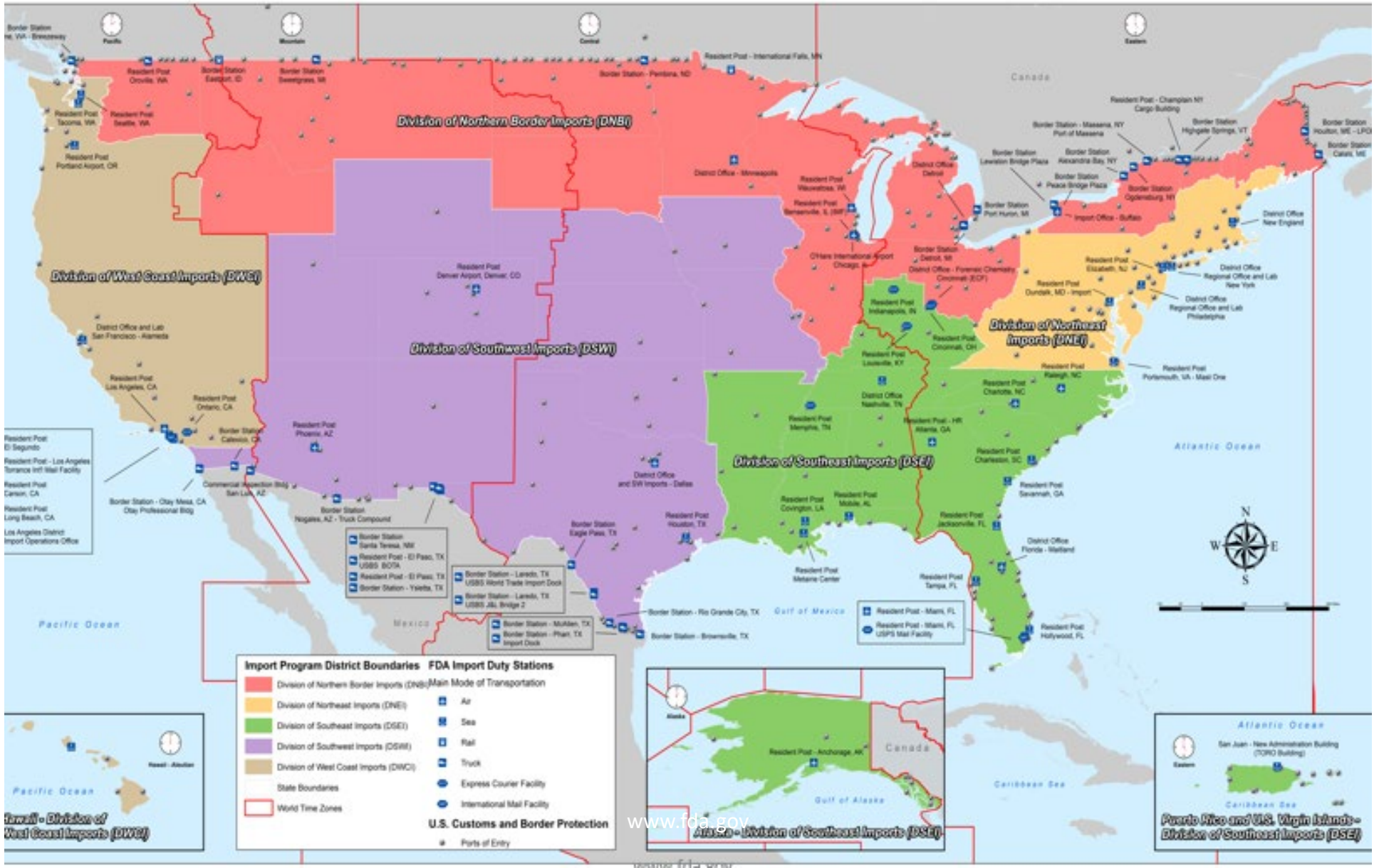
Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs



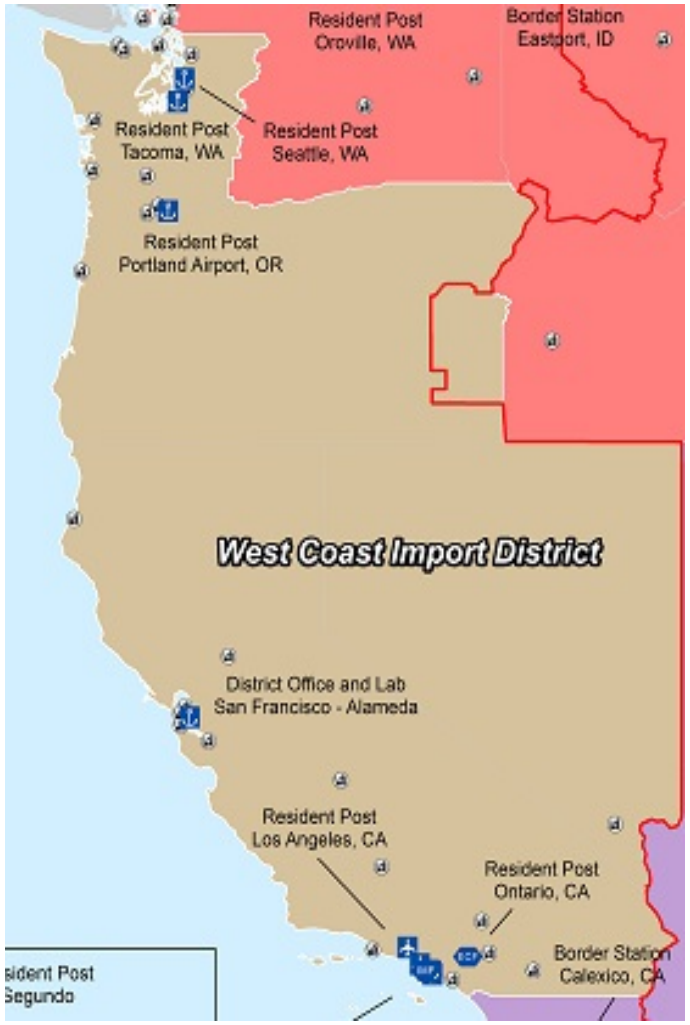
Office of Enforcement and Import Operations



Office of Enforcement and Import Operations (OEIO) Program Divisions with Duty Stations and CBP Ports of Entry



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)

Division of West Coast Imports Org. Structure

DIVISION DIRECTOR

INVESTIGATIONS BRANCH

- Release or May Proceed your products
- Import Product Review
- Inspect Products
- Sample Collections
- Request Detentions
- Investigations
- Inspections
- Refusal Exams
- Recall
- Filer Exams
- Seizure of Products at the Border

COMPLIANCE BRANCH

- Release or May Proceed your products
- Import Product Review
- Retail Samples Exam
- Label Review
- Request Investigations
- Detain Shipment
- Refuse Shipment
- Recondition Review
- Seizures
- Injunctions/Debarment
- Initiate Criminal Case to Agents

Imports 101

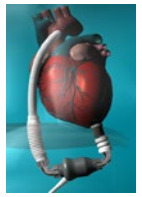
- Imported shipments of FDA-regulated products must comply with the same standards as domestic products.
- These products are screened by FDA before they enter the U.S.
- Products may be refused entry if they have been adulterated or misbranded, or are forbidden/restricted for sale.
- Products that do not comply with U.S. requirements may be refused admission and must be destroyed or exported from the United States within 90 days.

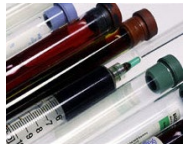
General Import Process

Customs Broker

Human and Animal Food

Drugs | Medical Devices | Biologics | Tobacco

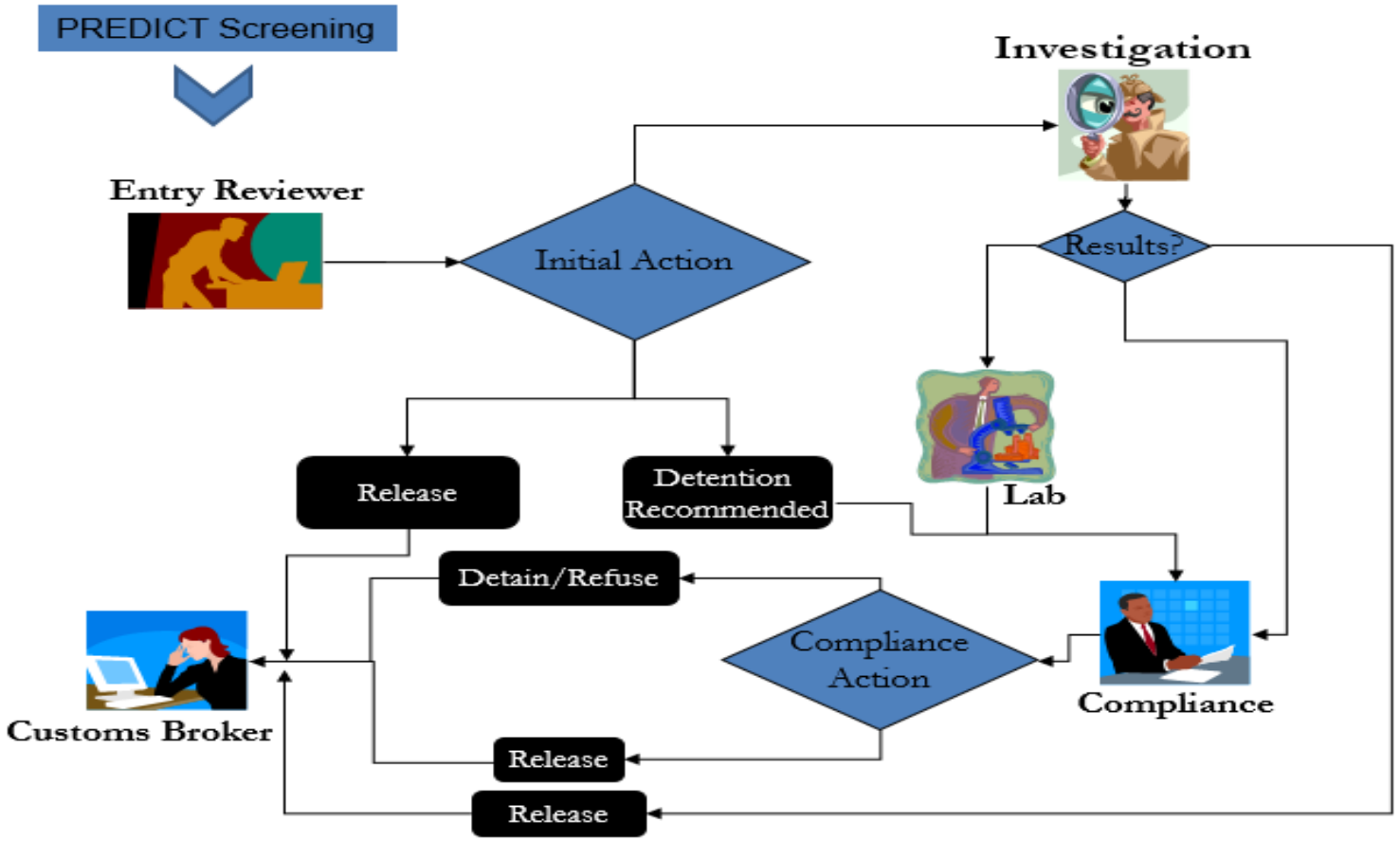




DIVISION OF FOOD DEFENSE TARGETING (DFDT)

PREDICT Screening

General Import Process Cont…



Import Field Examinations

Import Sample Collections

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Division Of West Coast Compliance Branch

Who Are We?

DWCI's Compliance Branch enforces the laws regulated by FDA.

- **Perform final admissibility decision**
- **Seek voluntary compliance**

FDA'S Import Authority

Defined in Federal Food, Drug, and Cosmetic Act in 801(a)

…if the article "appears" from the "examination of such samples or otherwise"…to be violative…it

"shall" be refused admission

Importing Process

Compliance Officer Reviews Case

- Release
- Detain/Detention Without Physical Examination (DWPE)
- Refusal

Importing Process: Detention

- FDA Notice of Detention issued when product appears to be violative

- 21 CFR 1.94 – If it appears that an imported article may be subject to refusal of admission, the FDA shall give the owner or consignee a written notice to that effect

Importing Process: Detention

- 21 CFR 1.94 – Hearing on refusal of admission
  - 10 days response time

- Importer's Options
  - Contest or Challenge
  - Recondition
  - Request for Refusal (to Destroy/Export)
  - Abandon Entry (No response - Results in Refusal)

Importing Process –Import's Options

- **Request authorization to recondition or re-label (submit Form FDA-766)**

- **21 CFR 1.95 – Application for authorization to re-label or…to bring the article into compliance or to render it other than a food…shall be filed by owner or consignee…and shall**

    1. **Contain detailed proposal**
    2. **Specify the days needed and location**

Importing Process – Importer's Options

- **21 CFR 1.96 – When authorization…is granted, the FDA shall notify the applicant in writing specifying:**

  1) Procedure to be followed

  2) Disposition of rejects

  3) Supervision by FDA or CBP

  4) Time limit for completion

Importing Process –Importer's Options

- **Contest or Challenge**
  - **Present testimony/evidence to overcome the apparent violation**
    - **Private Lab analysis**
      - **Provide Collection Report**

Importing Process –Import's Options

- If requesting an extension
  - Within 10-days
  - Details of the request
    - Resolution being pursued
    - Not excessively long (for most situations, should not take longer than 10 working days)
    - Reasonable Basis
  - Days requested
    - No more than 30-days (most situations, start of detention to final admissibility)

Importing Process

- Release After Reconditioning or
- Refusal
  - Reconditioning criteria not met
  - Product remains in violation

Importing Process

FDA Notice of Refusal

- Final Action of the agency
- US Customs Notified to issue the Demand for Redelivery (CF-4647)
  - Destruction (CF-3499)
  - Exportation (CF-7512)
- If importer fails to redeliver, liquidated damages may be accessed by CBP

Importing Process

- READ the Notice of FDA Action
- Provide a complete response
- If reconditioning denied, ensure your final attempt is complete
- Respond within the identified hearing period
- Do not wait on the last date of the hearing period to take action
- Importer's Certification of completion

ITACS Entry Status

- Check status in ITACS by entry number. (https://itacs.fda.gov)
- ITACS allows you to
  - Submit entry documentation
  - Submit availability for FDA exam
  - Check estimated completion dates for samples
  - Receive FDA Notices of Action

Communication with Division of West Coast Imports

WCID@fda.hhs.gov

- Provide Entry Number
- Give Brief Description of Product

Questions


Thank You!
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