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

Update on FDA Food Imports

LA Chamber of Commerce

March 13, 2018

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Division Director

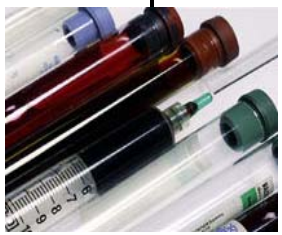
FDA AUTHORITIES

Office of Regulatory Affairs

Office of International Programs

Center for **F**ood **S**afety & **A**pplied **N**utrition

Center for **D**rug **E**valuation & **R**esearch



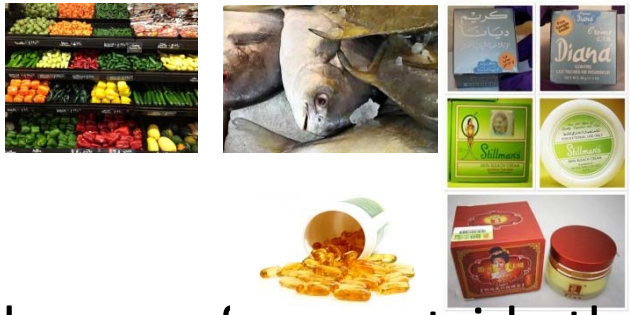
Center for **B**iologics **E**valuation & **R**esearch

Center for **D**evices & **R**adiological **H**ealth

Center for **V**eterinary **M**edicine

Center for **T**obacco **P**roducts

Globalization of Production



Food

- 50% of fresh fruits
- 20% of fresh vegetables
- 80% of seafood eaten domestically come from outside the U.S. Other agencies have it higher.

Devices

- 42% of all medical devices used in the U.S. are imported

Drugs

- 80% of API used in the U.S. are manufactured abroad
- 40% of finished drugs are manufactured abroad

Globalization: Old Shenzhen

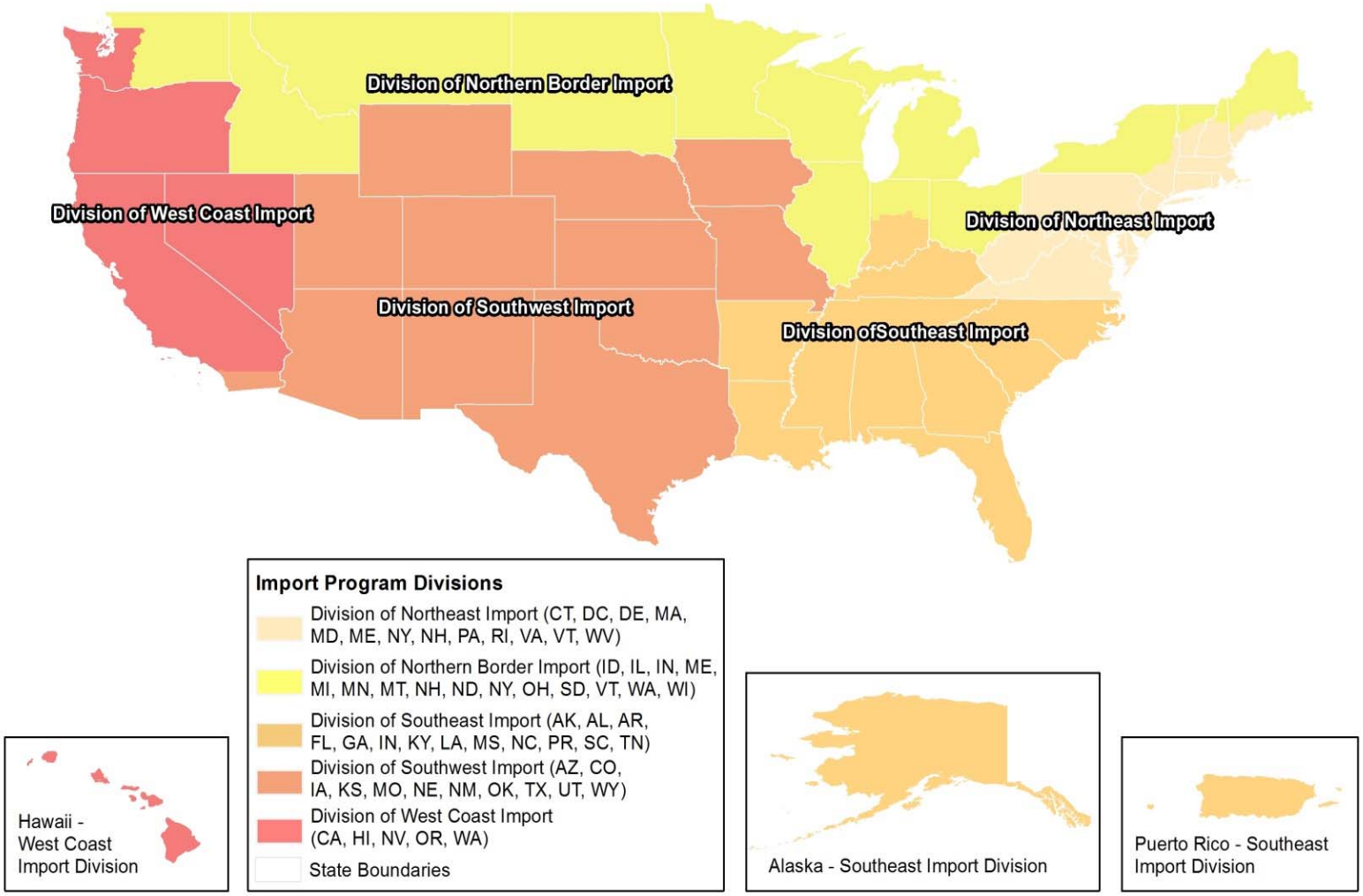
Globalization: Shenzhen Today!

What's New in FDA Import Operations- nationally and locally

- **On May 15, 2017 FDA/ORA was Program Aligned**
- **Consolidated Import Operations from 16 Districts to 5 Import Divisions (North, South, West and 2 in the East) = 5 Import Program Directors reporting to OEIO**
- **Will provide uniform and consistent application of Import Procedures through one office.**
- **Will provide more standardized training and operating procedures.**
- **Will help Improve communication and correspondence with FDA Port Offices and expedite review and release of compliant shipments.**

Office of Enforcement and Import Operations (OEIO)

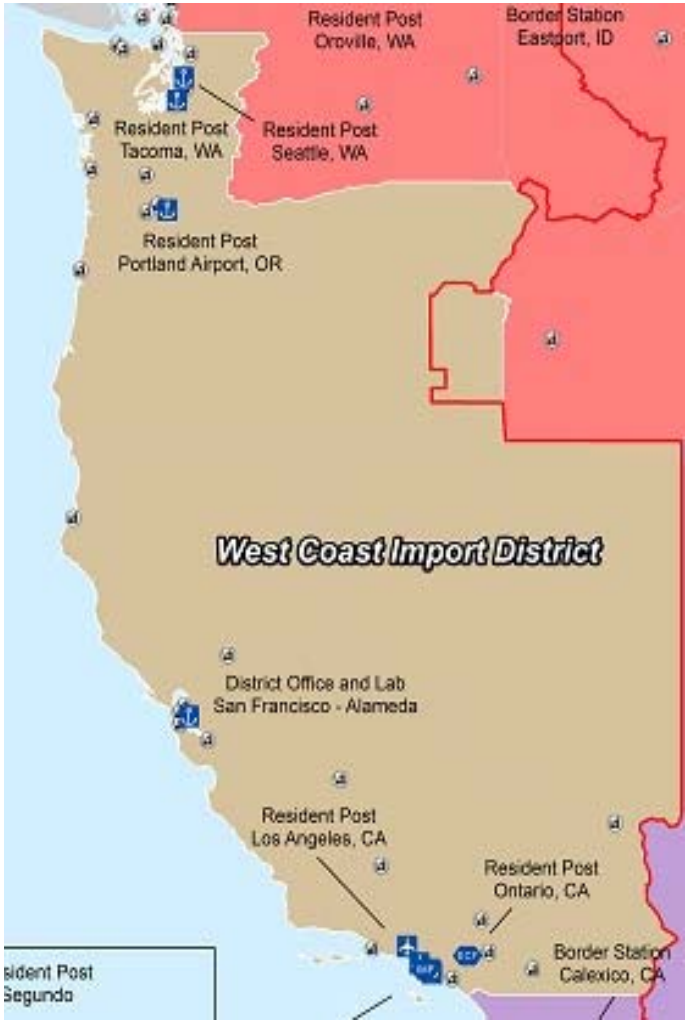
FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS



Source: ORA

Prepared by Office of Regulatory Affairs (ORA) Division of Planning, Evaluation & Management (DPEM), Program Evaluation Branch, 2017

Division of West Coast Imports



MAIN IMPORT OPERATIONS OFFICE – Long Beach, CA

Airports

Seaports

CENTRALIZED EXAMINATION STATIONS (CES)

International Mail Facility (IMF)

States of:

- California
- Oregon
- Washington
- Nevada
- Hawaii

GENERAL IMPORT PROCESS

Mandatory Fields

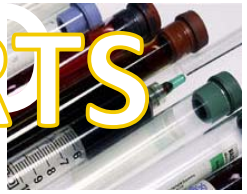
Human and Animal Food

Pharmaceutical | Medical Device | Biologics | Tobacco

DIVISION OF FOOD DEFENSE TARGETING (DFDT)

(formerly the PRIOR NOTICE CENTER)

IMPORTS



PREDICT/District Screening and Review

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FDA's New Food Legislations

- **Food Safety Modernization Act (FSMA**). Signed into law on January 4, 2011.
- The most sweeping reform of **our food safety laws in more than 70 years**.
- It aims to ensure the U.S. food supply is safe by shifting the focus **from responding to contamination to preventing** it.

  - Seven Foundational Rules:
    - Produce Safety
    - Preventive Controls for Human Food
    - Preventive Controls for Animal Foods
    - Foreign Supplier Verification Program (FSVP)
    - Accreditation of third-party auditors for foreign facilities
    - Mitigation for Intentional Adulteration of Food
    - Sanitary transportation of Human and Animal Food

Key Principles of FSVP Rule

- Requires importers to share responsibility for ensuring safety of imported food
- Risk-based (according to types of hazards, importers, and suppliers)
- Flexibility in meeting requirements (assessing activities conducted by others)
- Alignment with PC supply-chain provisions

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What is an FSVP?

- FSVP = Foreign Supplier Verification Programs

- It is a program that **importers covered by the rule must have in place to verify that their foreign suppliers** are producing food in a manner that provides the **same level of public health protection as the preventive controls or produce safety regulations**, as appropriate, and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.

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Standard FSVP Requirements

- Develop FSVP
- Conduct Hazard Analysis
- Evaluate Risks Posed by a Food and Performance of the Foreign Supplier
- Approval of Foreign Supplier
- Foreign Supplier Verification Activities
- Corrective Actions
- Maintenance of Records

Goal: You want to show the FDA Investigator that you are taking steps to ensure the food you have imported are safe and are not misbranded

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Who Must Comply?

- "Importer" is U.S. owner or consignee of a food at time of U.S. entry.

- If no U.S. owner or consignee at entry, importer is U.S. agent or representative of the foreign owner or consignee, as confirmed in signed statement of consent.

FSVP Importer – Key Points

- FSVP Importer may or may not be the CBP Importer of Record.
- Regulation is specific as to who the FSVP importer is and that they are to be located in the US.
- At time of Entry the owner of the product is the FSVP importer.
- **Communication i**s key for the Importer of Record and the FSVP Importer before you Import.

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What is VQIP?

- Voluntary Qualified Importer Program
- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants.
- Eligibility is limited to importers who demonstrate a high level of control over the safety and security of their supply chains.
- VQIP Importer is “the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.”
- Final guidance can be found here:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm448574.htm

Timing of VQIP Program

- Guidance for Industry published November 2016
- First AB recognized January 31, 2018
- Applications accepted January 31 – May 31, 2018
- First benefit period to begin October 1, 2018
- **How do I apply?**
  - Visit the FDA Industry Systems website to establish an online account.
  - From January 1 to May 31 each year, submit online a "Notice of Intent to Participate" in VQIP.
  - Your VQIP application must be renewed each year.

Draft Benefits of VQIP

- Expedited entry into the U.S. for all foods included in an approved VQIP application.
- Examination and/or sampling generally limited to “for cause” situations in which there is a potential threat to public health.
- Any sampling or examination done at destination or another location chosen by the importers
- Expedited laboratory analysis of any samples
- VQIP importers Help Desk.
- Public posting on the FDA’s VQIP web page of approved VQIP importers, if desired.

Questions

- VQIP Importer's Help Desk
  - M-F 8am – 8pm EST
  - FSMAVQIP@fda.hhs.gov
  - 1-301-796-8745
- Website: https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm490823.htm

Food Registration

- The **Public Health Security and Bioterrorism Preparedness and Response Act of 2002** (the Bioterrorism Act) directs the Food and Drug Administration (FDA), to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.
- To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that:
  - Food facilities register with FDA, and
  - FDA be given advance notice on shipments of imported food.

Food Registration

- **FDA Food Safety Modernization Act (FSMA)**, amended section **415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act),** in relevant part, to require that facilities engaged in **manufacturing, processing, packing, or holding food** for consumption in the United States submit additional registration information to FDA.
- Section 415 requires food facilities required **to register with FDA to renew such registrations every other year,** and provides FDA with authority to suspend the registration of a food facility in certain circumstances. FDA may by order suspend the registration of a facility.

Food Registration

- All food facility registrations are required to be submitted to the FDA electronically, although this requirement does not take effect until **January 4, 2020**.
- **Who Must Register?**
  - If you are the owner, operator, or agent in charge of either a **domestic or foreign facility that is engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the United States,** you must register with FDA, unless you are exempt under 21 CFR 1.226 from the requirement to register.
  - If you are an owner, operator, or agent in charge of a **domestic facility,** you must register your facility **whether or not the food from the facility enters interstate commerce** (21 CFR 1.225(b)).
  - If you are the owner, operator, or agent in charge of a facility**, you may authorize an individual to register your facility on your behalf** (see 21 CFR 1.225(c) and 1.230(a)). **A foreign facility's U.S. agent may, but is not required to, register the facility** (21 CFR 1.230).

Food Registration

- More information can be found here:

https://www.fda.gov/forindustry/fdabasicsforindustry/ucm234625.htm

- Food Licensing
  - In the state of California:
  - California Department of Public Health (CDPH) – Food and Drug Branch (FDB)
  - CA registration and licensing
  - https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram.aspx
  - City of Los Angeles – business licensing requirements

FDA LEADERSHIP

Dr. Scott Gottlieb was sworn in as the 23rd Commissioner of Food and Drugs on May 11, 2017.

"FDA always faces big challenges because of where it sits at the intersection of so many critical concerns. By virtue of the fact that people's lives – quite literally – depend on what we do."

Thank You For Your Attention!

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Thank you!

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FDA
U.S. FOOD & DRUG
ADMINISTRATION