

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



*PIHOA
Pago Pago, AS*

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Dan Solis
Division Director



Outline

- What has changed in FDA?
- FDA Reorganization – Program Alignment
- Continued work in the Pacific with FDA and Pacific Leadership
- How can FDA help?
- Next Steps

What has changed in the US Food and Drug Administration



- **New Commissioner** – Dr. Scott Gottlieb was sworn in as the 23rd Commissioner of Food and Drugs on May 11, 2017. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs and before that, as a senior advisor to the FDA Commissioner.
- **FDA Reorganization – Program Alignment**
- **Why Program Alignment?**

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.”

Why Program Alignment?

Globalization of Production



Food

- >50% of fresh fruits
- >30% 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!

FDA



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



Why Program Alignment? New Food and Drug Legislations



- **Food Safety Modernization Act (FSMA)**. Signed into law on January 4, 2011.
- **Food and Drug Administration Safety and Innovation Act (FDASIA)**. Signed into law on July 9, 2012.
- Other laws and responsibilities...

Continue Work In the Pacific

- **Work by Regional Office**
- **Work by San Francisco District and San Francisco Lab**
- Inspectional Work in Food, Drug and Medical Devices will continue
- Emergency Deployment and support will continue
- Collaboration with FDA labs and technical support will continue

New FDA Import Operations Website

- New Imports Program website:

[http://www.fda.gov/ForIndustry/ImportProgram/
default.htm](http://www.fda.gov/ForIndustry/ImportProgram/default.htm)

- New Product Code Builder website:

[http://www.accessdata.fda.gov/scripts/ora/pcb/
index.cfm](http://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm)



New Import Alerts Website

- **Import Alerts** = Import alerts **inform FDA field staff** and the public that the agency has enough evidence of products that appear to be in violation of FDA laws and regulations. These violations could be related to the **product, manufacturer, shipper and/or other information**.
- [LINK](#)
- <http://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/default.htm>



How can FDA help?

- Need to know the Food, Drug and Medical Device Issues the islands are encountering
- Learn trends and what is going on
- Suggests ways FDA can communicate and offer information and technical assistance
- Ongoing commitment since we have FDA Consumer Safety Officers (CSO) that will conduct Foreign Inspections and also 8-9 FDA CSO's in Honolulu, HI
- Continued Information exchange



FORMS OF COMMUNICATION WITH FDA in West Coast

- **Phone Numbers for Division of West Coast Imports Office in Long Beach, Ca**
 - **General status line (562) 256-7700**
 - **Compliance status line (562) 256-7707**
 - **Fax line (562) 256- 7701**
- **General email address: WCID@fda.hhs.gov**
- **Los Angeles District Consumer Complaint Hotline: (949) 608-3530**
- **FDA National Emergency Operations Number: 1-866-300-4374 or (301) 796-8240**
- **FDA General Inquiry: 1-888-INFO-FDA**
- **For Adverse Event of illness call 1-800-FDA-1088 or [online](#)**
- **For Drug Inquiries: CDERSmallBusiness@fda.hhs.gov or (866)-405-5367**
- **For Medical Device Inquiries: industry.device@fda.hhs.gov or (800) 638-2041**
- **To report e-mails promoting medical products that you think might be illegal, forward the email to: webcomplaints@ora.fda.gov.**
- **Food and Cosmetic Information Center by phone and/or e-mail Monday through Friday, from 10 a.m. to 4 p.m. at 1-888-SAFEFOOD (1-888-723-3366). Or, submit questions by [filling out the online form](#).**

Note: Fastest response is email.

Thank You For Your Attention!



Email address:
Dan.Solis@fda.hhs.gov

Or

WCID@fda.hhs.gov



Thank you!



www.fda.gov