• IMPORT OPERATIONS

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OEIO/Division of Southwest Imports
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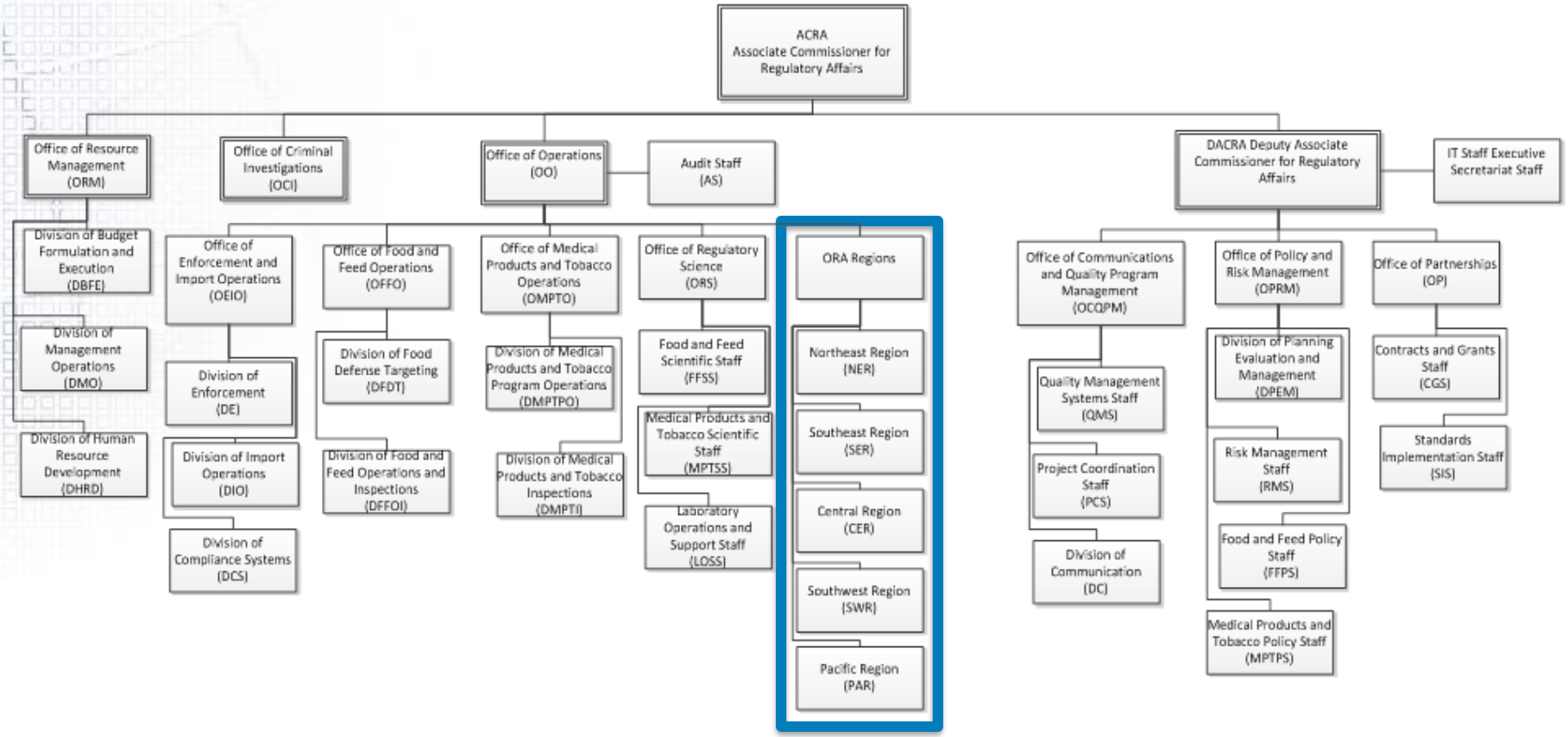
PRESENTATION OVERVIEW

General Overview of U.S Import Operations

- ✓ FDA Organization
- ✓ Field Activities
- ✓ Import Process

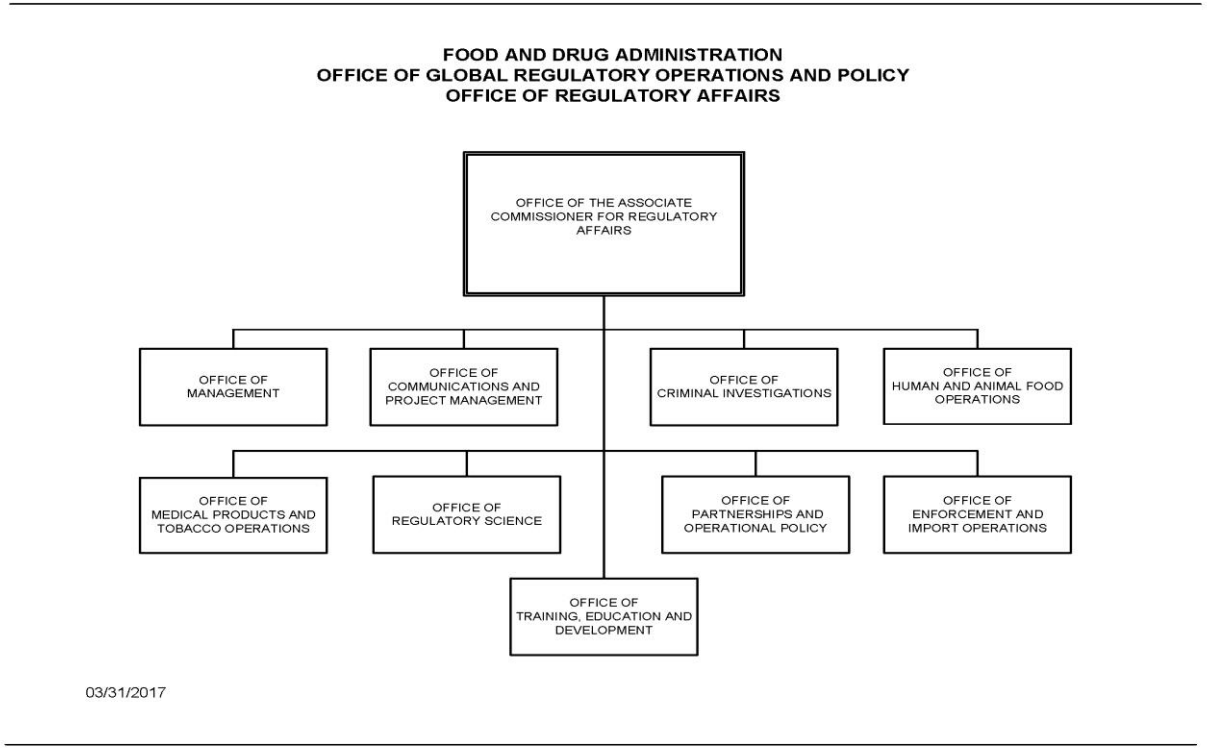
OLD

Geographically Aligned Organizational Model



New

Program Aligned Organizational Model



Program Alignment: Key Changes

From	To
Geographic management of operations	Program management of operations, management teams based on staff: • Bioresearch Monitoring — 2 management teams • Biologics — 2 management teams • Human and Animal Food — 12 management teams • Medical Device and Radiological Health — 3 management teams • Pharmaceutical Quality — 4 management teams • Tobacco • Plus Imports as a program — 5 management teams
SES Regional Food & Drug Directors	SES Program Directors
Degrees of program specialization for investigations, compliance and operational managers	Exclusive specialization in one program for investigations, compliance and operational managers
20 District Directors who manage the geographic district and all programs operations within the district	20 District Directors who manage the geographic district and only one program for operations. Plus eight new program division directors who manage program operations only – total 28 management teams
One import district and a range of import operations embedded within the 16 other districts	Five import divisions (four new import divisions) covering all borders, managing import operations nationally as a program

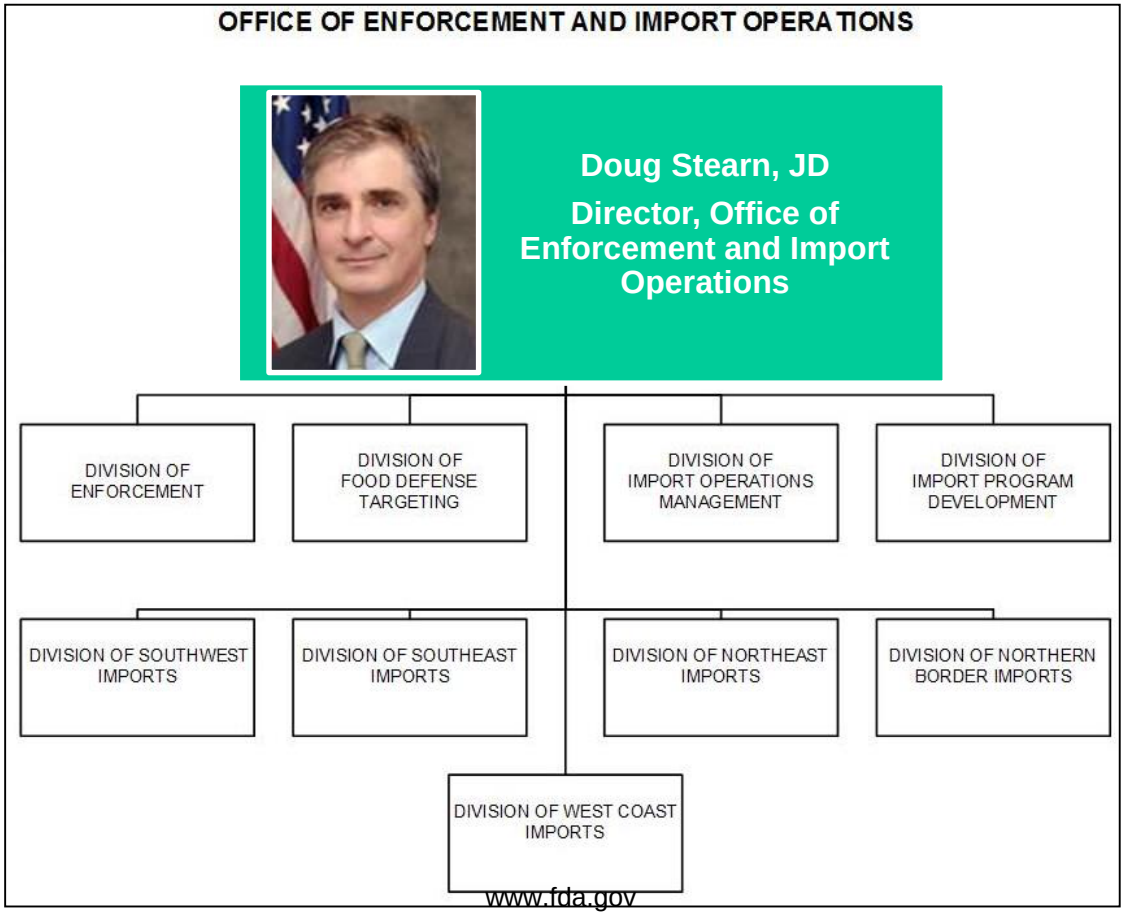
Offices of…

Melinda Plaisier, MSW
Associate Commissioner for Regulatory Affairs

Doug Stearn, JD
Director, Office of Enforcement and Import Operations

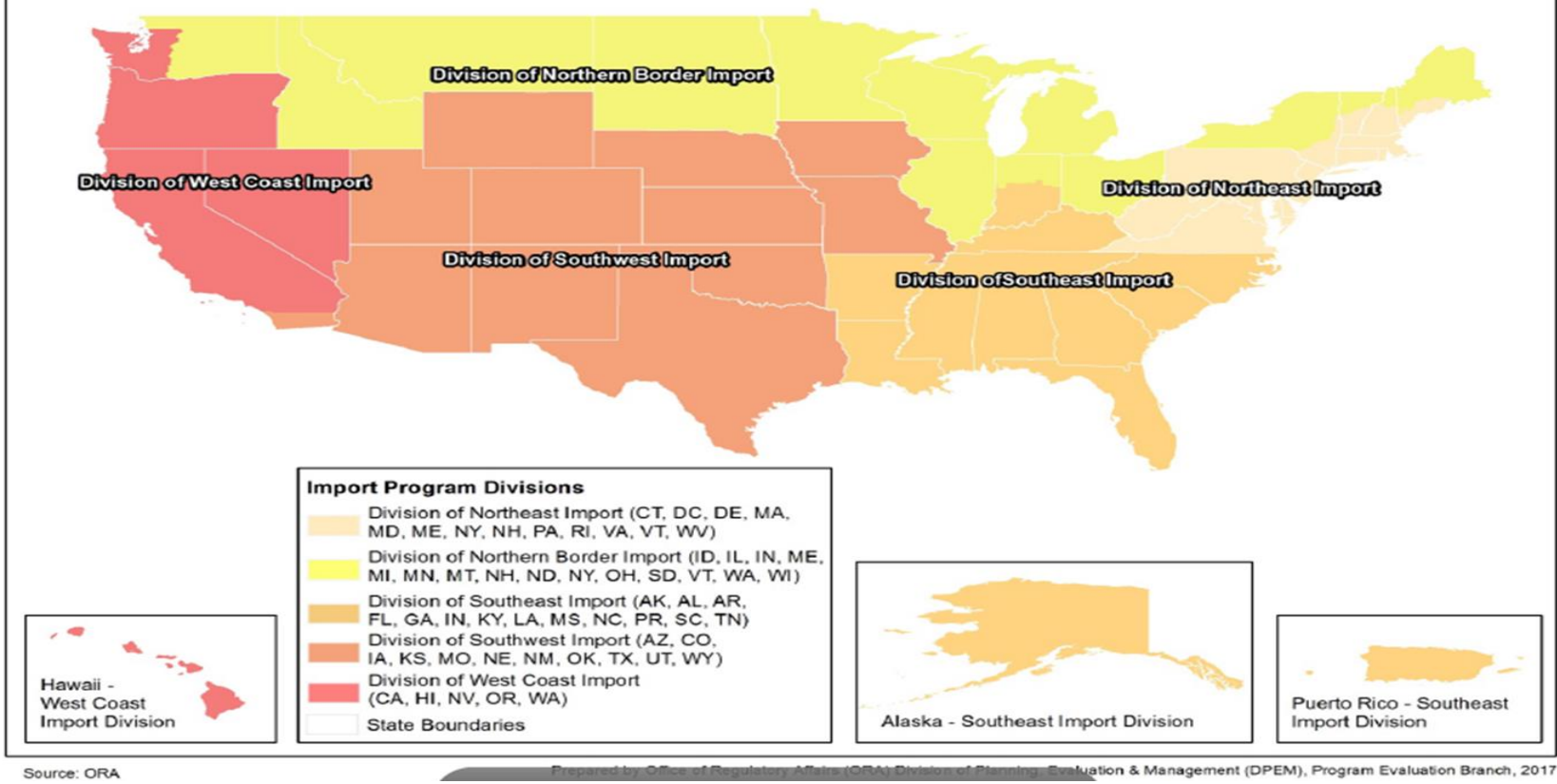
Paul Norris, DVM, MPA
Director, Office of Regulatory Science

Office of Enforcement and Import Operations



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

Import Process

- **Section 801 of the FFD&CA**

"If it appears from the examination of such samples *or otherwise* that…"

(1) such article has been manufactured, processed, or packed under insanitary conditions… or

(2) such article is forbidden or restricted in sale in the country in which it was produced … or

(3) such article is adulterated, misbranded, or in violation of section 505 (New Drugs)

"then such article shall be refused admission…"

The Import Process

Field Activities

- **Field Activities**
  - Electronic entry screening
  - Field examinations
  - Label examinations
  - Sample collections and analysis (testing)

The Import Process

- **An importer or a designated representative must file an entry and an entry bond with Customs pending a decision to allow the goods into the U.S.**
- **Notice must also be filed with FDA**
- **Investigators evaluate the admissibility of a product electronically**
- **Entry reviewers have several options:**
  - ✓ Release the product
  - ✓ Request examination of the product
  - ✓ Request additional information or documents
  - ✓ Recommend detention of the product

The Import Process

Field Activities

- **Compliance Activities**
  - Detentions
  - Releases
  - Hearings and Review
  - Reconditioning Supervision & Review
  - Refusals
- **Post-Refusal**
  - Export Verification
  - Witness the Destruction
- **Entry Filer Activities**
  - Filer Evaluations
  - Filer Training

DOCUMENT REQUEST/ INFORMATION

NOTICE OF FDA ACTION

ACS/ PRIOR NOTICE

OASIS

FOOD

PN Satisfied

Admissibility

FDA HOLD

IMPORTER

CUSTOMS HOUSE BROKER (CHB)/FILER

CHB SOFTWARE

ENTRY REVIEW

Prior Notice Center

EXAMINE

- LABEL
- CONTAINER INTEGRITY
- SAMPLING
- VERIFICATION

EXPORT or DESTRUCTION

DATA

REFUSED

EXAMINE

LAB

ABI

RECOMMEND DETENTION

PNC HOLD

DISCLAIMER

LAB REPORT

DATA

MAY PROCEED

US COMMERCE SYSTEM

In Compliance

COMPLIANCE OFFICER

Appearance of a violation

DETAINED

~ 10 days

"TESTIMONY"

RELEASE

overcome the appearance

REFUSED

Fail to overcome the appearance

EXPORTED

~ 90 days

CBP

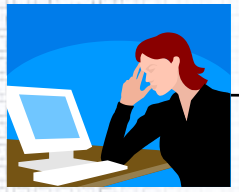
~ 90 days

DESTRUCTION

U.S. Department of Health and Human Services

Food and Drug Administration

Electronic Transactions
Import Entry Lines



Entry filer

Firms, product code

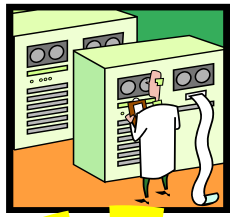
Customs

foods

others

OASIS

PN screening – food

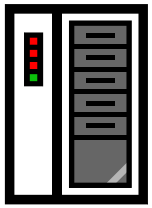


foods

Prior Notice Center

PREDICT

801(a) screening



Yes

OK?

No

"FDA review" message

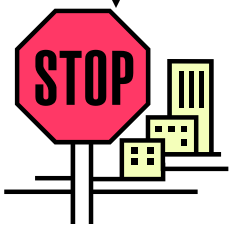
"May proceed" message

FDA district entry reviewer

No

Review?

Yes



FDA district entry reviewer

Documents requested by FDA

Initial action?

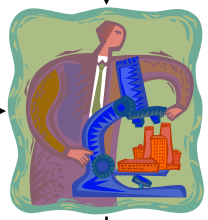
Field exam

???

Results?

Good

Bad



Sample, analyze

"May proceed" message

Detain w/o physical exam

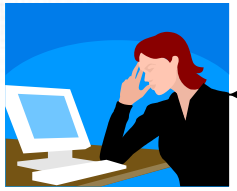
Detain

Release with comment

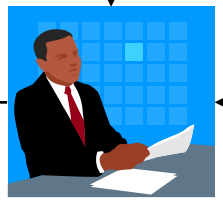
Release

Compliance action

IB release



Entry filer



Compliance Officer

The Import Process

If FDA allows the product to May Proceed

- Product may be distributed
- FDA still has jurisdiction
  - Import Status – Level of Proof only an "appearance"

    vs.
  - Domestic Status – We need an actual violation
- Does not preclude FDA action if a problem is found later

The Import Process

- **FDA can detain based upon "appearance" of a violation**
  - "Appearance" can come from:
    - Facility Inspection
    - Examinations
    - Sampling
    - Laboratory examination
    - Historical Data
    - Lack of required processes and/or approvals
    - Other sources, eg. a disease outbreak involving an FDA regulated product
    - Labeling
    - Reports from other Governmental and State Agencies

The Import Process

- **Regardless of the nature of the detention:**
  - ✓ Importer has the right to give evidence to refute the appearance of a violation
  - ✓ Based on the evidence, the detention will either stand (refusal) or be overturned (released)
- **Importer can also petition to recondition the goods to bring them into compliance**
  - ✓ Relabeling a misbranded product
  - ✓ Cleansing an adulterated product
  - ✓ Making a product not FDA regulated
- **Reconditioning must be approved by FDA**

The Import Process

- If a product can not be brought into compliance, the product will be refused entry
- Refused product may be exported or destroyed
- A redelivery notice will be issued upon refusal
- CMP (civil money penalty) if products are not exported or destroyed
- FDA does have authority to seize product if certain criteria have been met

Import Entry Review

- Entries can be selected for examination for multiple reasons, but most often for the following:
  - High Risk (Microbiological)
  - Past History (Manufacturer / Product)
  - Surveillance
  - Non Compliance (Labeling)
  - Import Alerts

Field Examinations

- Invoices
- Labeling
- Integrity of shipment
- Cleanliness of product
- Refrigeration
- Quick Lead Tests

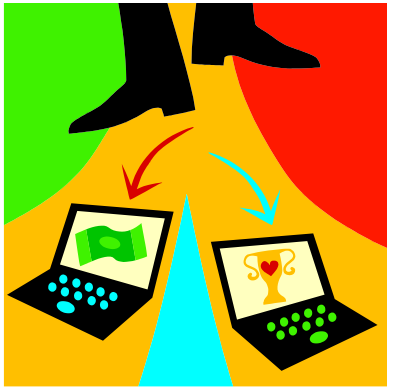
Sample Collections

- Microbiological Hazards Analysis
- Pesticide Analysis
- Color Additives Analysis
- Food Additives Analysis
- Aflatoxin Analysis
- Filth Analysis

Sample Collections

- Once an entry is sampled, the U.S. Customhouse Broker, Importer of Record, and Consignee (if specified) will receive a written notification "**Notice of Action** " from the local FDA office on the type of sample collected and reason for collection.

The Import Process
Release



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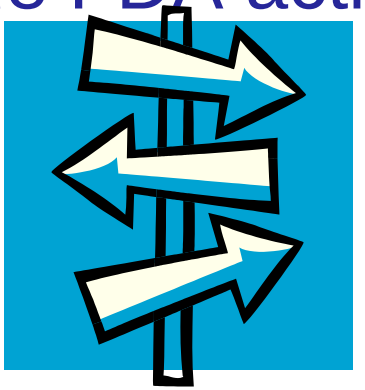
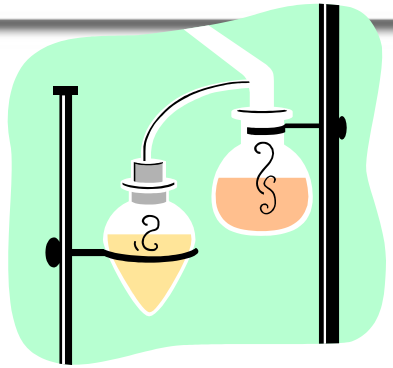


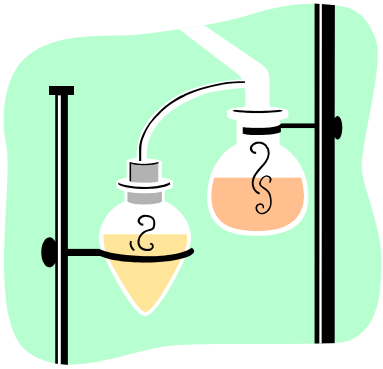
RECALL

What is the status of my ENTRY???

Sample collected

Documents requested





Location of product

https://itacs.fda.gov

Status of Sample Collected

SwidSampleStatus@fda.hhs.gov

Welcome to the Division of Southwest Import-Dallas

- We highly recommend using ITACS to submit entry documents and availability information at **http://itacs.fda.gov** Any questions or concerns regarding ITACS may be directed to itacssupport@fda.hhs.gov

- Filers, importers, and software developers may contact the ACE Support Help Desk for questions on how to transmit an ACE entry to FDA, what the requirements are, help in troubleshooting issues with an entry (how to resolve a rejection or discern error messages), or to request a teleconference to transmit an entry with FDA's assistance.

  To contact the FDA ACE Support help desk:
  Email: ACE_Support@fda.hhs.gov
  Call: 877-345-1101 (Toll Free) and 571-620-7320 (Local/International)

For general questions: or entry related questions: **DSWI- Dallas Office**

- **Main Line**:
  Phone: 214-253-5330 → opt. 1 for English → opt. 2 for Imports
  Entry Status Line: 214-253-5330 → opt. 1 for English → opt. 2 for Imports → opt. 1
  Entry status

- Email address for Dallas Import Investigations Team- Team 8 : Dallasimports@fda.hhs.gov

Thank You