



# Food and Agriculture Border Summit

## What You Really Need To Know About Importing into the US

Presentation by:

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# PRESENTATION OVERVIEW



## I. FSMA

## II. Some quick stats

## III. The 6 Things you need to know about the importing products into the United States

## IV. On-going priorities

- ✓ ORA HQ Changes
- ✓ PREDICT
- ✓ ITACS
- ✓ FSMA & FDASIA
- ✓ Pathway to Global Product Safety & Quality

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# FSVP Top issues

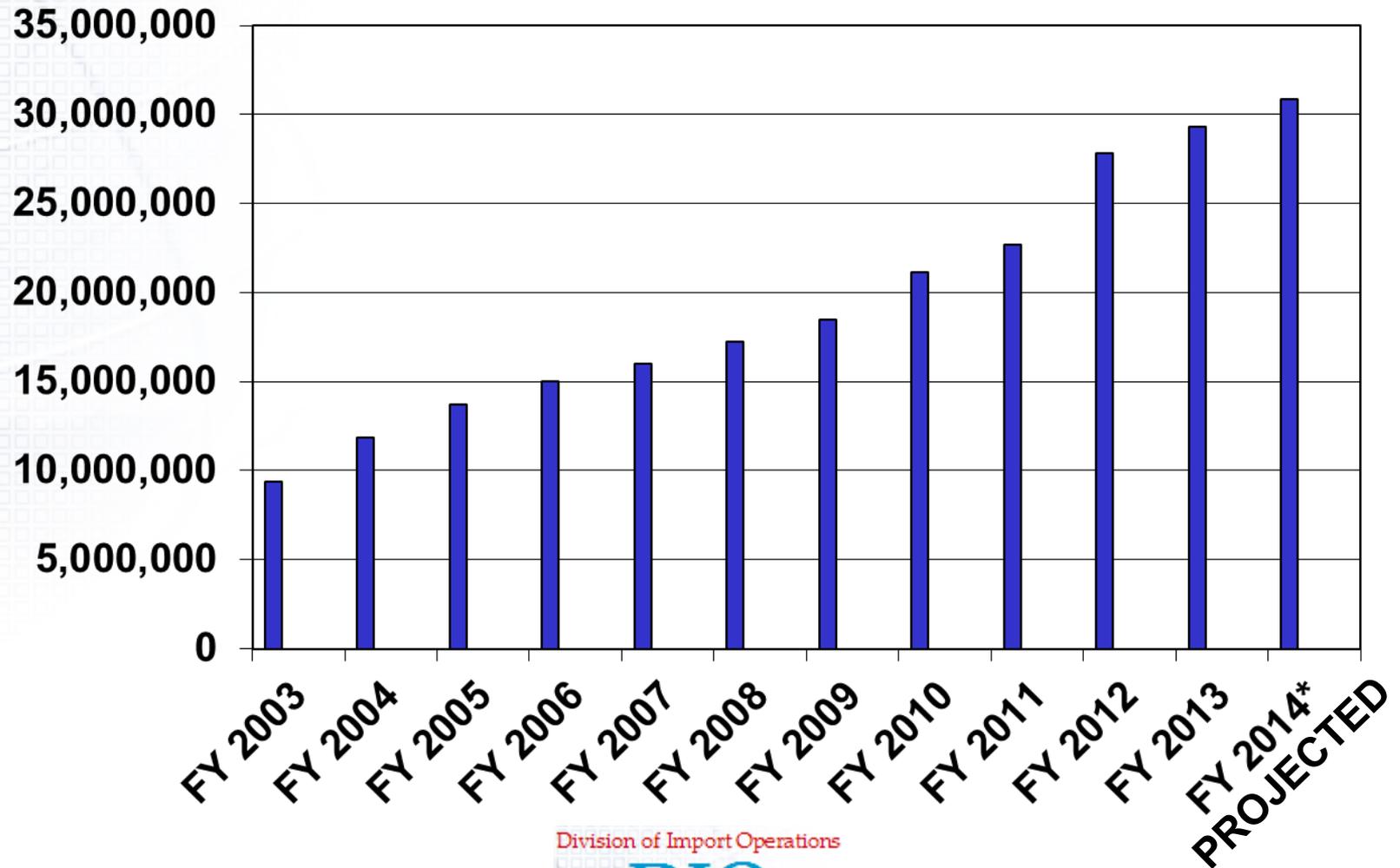


1. Option 1 vs. Option 2 for supplier verification activities
2. Definition of the foreign supplier – and how far back in supply chain the importer must verify
3. Definition of importer – especially when a U.S. agent or representative is involved
4. Definition of a qualified individual and who may serve as a QI
5. Documentation of audits (and confidentiality issues)
6. Whether to allow use of a report of a food safety authority inspection in lieu of an onsite audit
7. Proper definition of “very small” importers and foreign suppliers – and whether there should be modified provisions regarding these entities
8. Provisions on food from countries with comparable or equivalent food safety systems
9. Alignment of the FSVP requirements with supplier verification provisions in PC
10. Use of DUNS numbers to identify importers



# FY 2002 – 2014\*

## TOTAL IMPORT LINES

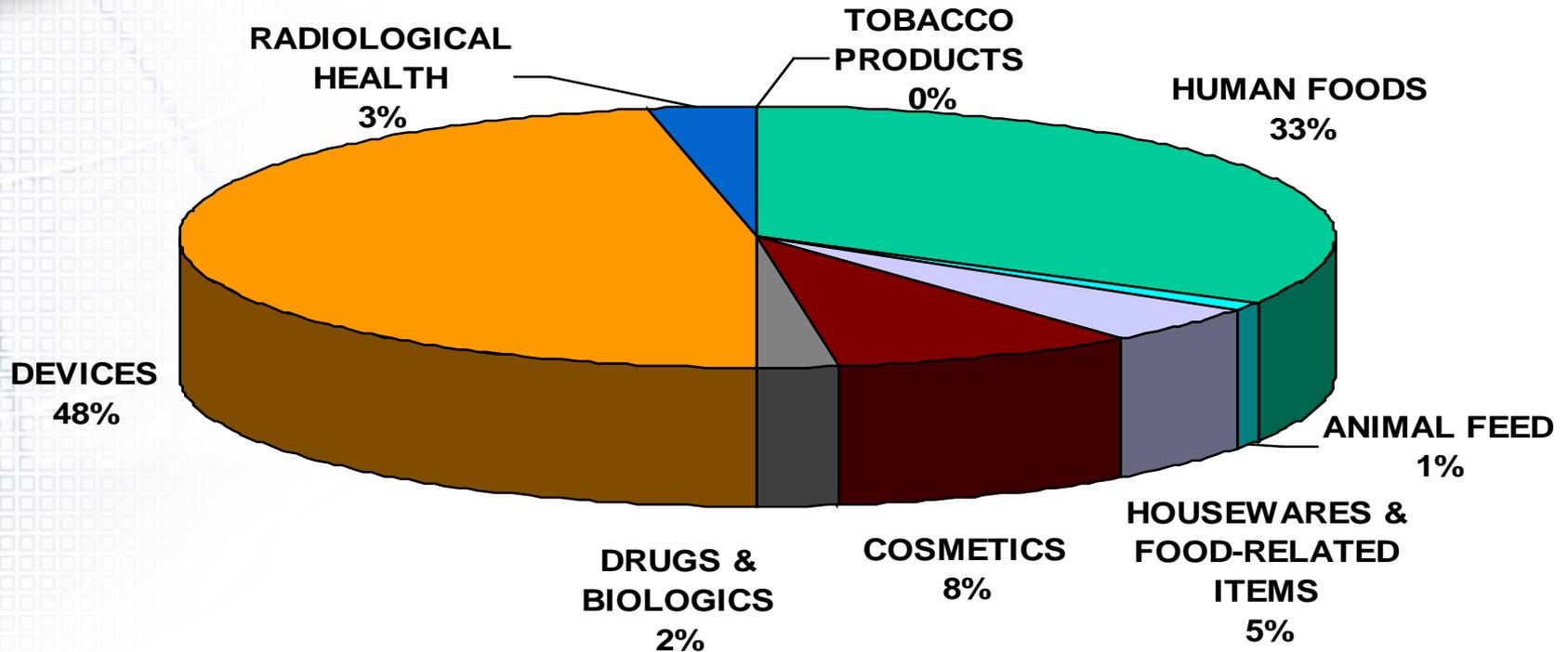


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# FY 2013 LINES BY CATEGORIES



■ HUMAN FOODS

□ HOUSEWARES & FOOD-RELATED ITEMS

■ DRUGS & BIOLOGICS

■ RADIOLOGICAL HEALTH

■ ANIMAL FEED

■ COSMETICS

■ DEVICES

■ TOBACCO PRODUCTS

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# 1. Know The Supply Chain:



## 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



## 2. Understand Section 801 of the FD&CA



### •Chapter VIII – Imports and Exports 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 **or the importer is in violation of section 805** or prohibited from introduction or delivery for introduction into Interstate commerce under Section 301(II)
- (4) **The recordkeeping requirements under section 204 of the FSMA (other than the requirements, under subsection (f) of such act) have not been complied with regarding such article**

“then such article shall be refused admission...”



## 2. Understand Section 801 of the FD&CA



### FDA can detain based upon “appearance” of a violation

#### ✓ “Appearance” can come from:

- Facility Inspection or refusal of 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



# 3. Know your Rights and the timeframes:



## ➔ 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



## 4. Understand the Import Alert System:



1. It prevents potential violative products from being distributed into the United States
2. It frees up Agency resources to examine other shipments
3. Provides uniform coverage across the country
4. Places the responsibility back on the importer
  - It is the responsibility of the importer to ensure that the products he is importing in the U.S. is in compliance with our laws and regulations



# 4. Import Alert System:



☞ 265 active Import Alerts

<http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm>

☞ Import Alerts:

- ✓ Provides guidance to the field that we have sufficient evidence to detain goods without examination

☞ # of Import Alerts

- ✓ Drugs 55                      Biologics 8                      Foods 141
- ✓ Devices 31                      Rad Health 6
- ✓ Vet meds 11                      cosmetics 13

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# 4. Import Alert System



## ☞ Removing a firm, product, or importer from DWPE:

- ✓ Firms or importers may petition to be removed from DWPE
  - Industry submits the petition
  - FDA reviews the petition
- ✓ Generally requires evidence of non-violative shipments but all depends on the Import alert
  - Firms with GMP violations may need an inspection to get off an IA
  - Analyzed by laboratory at importer expense
  - Documentation showing it isn't subject to the Alert
- ✓ FDA needs assurance the cause of the violation has been corrected

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## 5. Know the Required data elements and keep up to date with new legislation:



### Time Requirements for PN

<b>For Shipments arriving:</b>	<b>Time Requirement:</b>
By land via road	No Less than 2 hrs. before port of arrival
By land via rail	No less than 4 hrs. before port of arrival
By air	No less than 4 hrs. before port of arrival
By water	No less than 8 hrs. before port of arrival
By international mail	Before the food is sent
Carried by or otherwise accompanying an individual	Within the time frame for the applicable mode of transportation

*Minimum PN Time Frames Retained in PN Final Rule*

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## 5. Know the Required data elements and keep up to date with new legislation:



### PN data elements required:

### Not all inclusive

- Manufacturer (or Grower) - Name w/Food Facility Registration (FFR) # or \*Name w/site specific address & “Reason” why FFR # not provided.
- Shipper
- U.S. Consignee
- Country of Origin
- Product Identification
- FDA Product Code
- Anticipated Arrival Info
- Anticipated Shipment Info
- Importer
- PN Transmitter
- PN Submitter
- Entry Identifier

\* Change in Final PN Rule

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## 5. Know the Required data elements and keep up to date with new legislation:



### Admissibility Requirements for all commodities

#### ☞ Entry Data Elements (above what is required for CBP)

- ✓ FDA Country of Origin
- ✓ Name and address of Manufacturer
- ✓ Name and address of Shipper
- ✓ FDA Product Code

#### ☞ Certain food products require additional information to be submitted & evaluated by FDA:

- ✓ Low-Acid Canned Foods (LACF)
  - (FCE) Food Canning Establishment Number
  - Approved Scheduled Process Submission ID (SID#) and container dimensions
- ✓ Acidified Foods (AF)
  - Process for adequate acidification



## 5. Know the Required data elements and keep up to date with new legislation:



### Medical Products

#### ✓ Human Drugs

- Drug Registration Number
- Drug Listing Number
- Investigational New Drug Application Number (IND)
- New Drug Application Number (NDA)
- Abbreviated New Drug Application Number (ANDA)

#### ✓ Animal Drugs

- New Animal Drug Application Number (NADA)
- Abbreviated New Animal Drug Application Number (ANADA)

#### ✓ Biological Products

- Manufacturer's US Biologics License Number
- Product Biologics License Application Number or "Submission Tracking Number"

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## 5. Know the Required data elements and keep up to date with new legislation:



### Medical Products

#### ✓ **Medical Devices**

- Device Registration Number
- Device Listing Number
- Device Pre-market Approval Number (PMA)
- Device Pre-Market Notification Number (510(k))
- Investigational Device Exemption Number (IDE)
- Humanitarian Device Exemption Number (HDE)

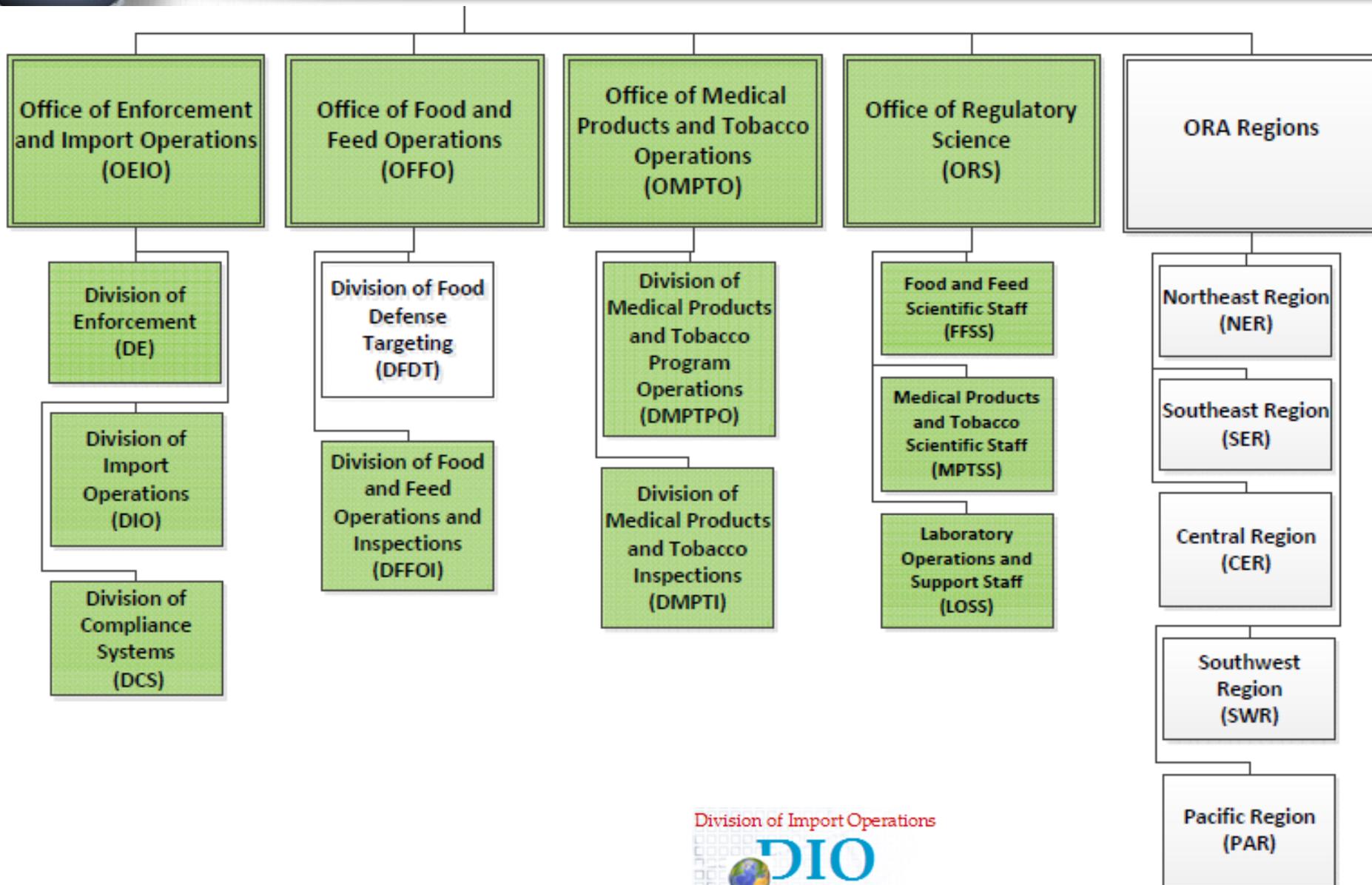
#### ✓ **Radiological Health Products – Electronic Non-Medical**

- Radiological Health Product Declaration
- Model Number
- RCHSA Accession Number

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## 6. Know the District Office & HQ for the port products are making entry



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# FY2014 Priorities



- ✓ PREDICT & ITACS
- ✓ FSMA & FDASIA
- ✓ ORA HQ Realignment
- ✓ The Pathway to Global Product Safety & Quality

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# FY2014 Priorities



- Evaluate & Redesign import structure
- Notice to Foreign Manufacturer
- IA Trend Analysis
- Internal SOPs (QMIS)
- CMS – enforcement capabilities
- IOM Updates
- HTS Flag review
- Uniform Contract
- CTAC Personnel
- ACE/ITDS
- WTO/TPP Trade Negotiations
- Train Staff
- Team Lead positions
- External (DHRD) Training
- Alternate IPM call and IC call each month
- QMS Feedback mechanism for cases
- CMS/Compliance case templates
- FSMA & FDASIA
- IOSP Entry Admissibility SOPs
- Center Training



# Import IT Projects



## **PREDICT Threshold Analysis**

- Develop commodity specific scoring and thresholds to improve Center rule alteration and increase system May Proceed rate

## **Medical Device Filer Outreach Report**

- Improve industry guidance through sharing of line level medical device data issues to reduce admissibility review time and increase system May Proceed rate

## **ITACS Account Management**

- Support enhanced communication with filers through implementation of a secure account system

## **Interoperability Web Services (IWS) Development**

- Programming of the IWS communication linkage between CBP and FDA under the ACE initiative



# Import IT Projects (cont.)

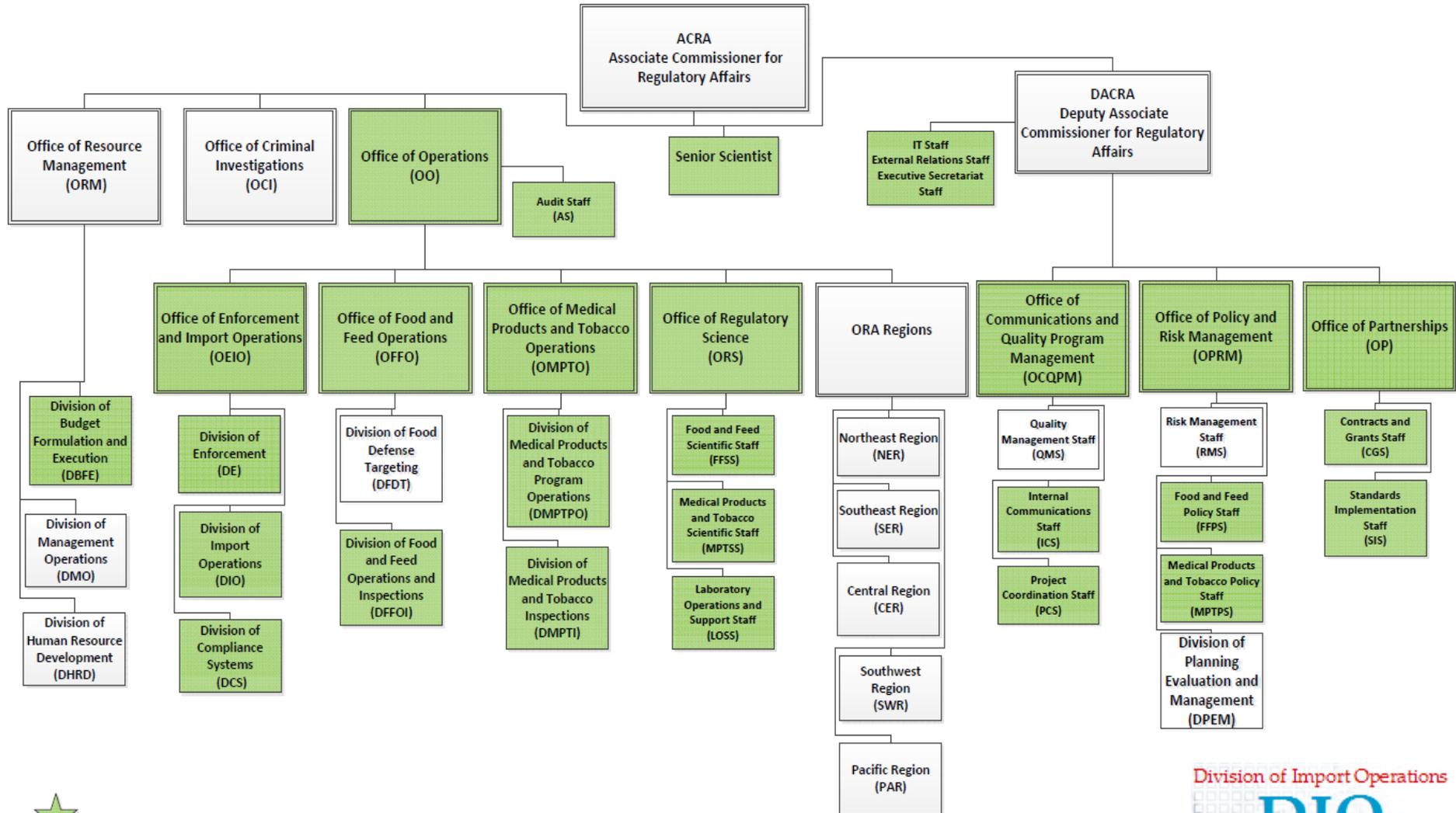


- ❑ **Decommissioning of Imports Unplugged**
  - ❑ Development of OASIS module to support drug reviews at the International Mail Facilities (IMFs)
  
- ❑ **ORADSS Imports and PREDICT Universe**
  - ❑ Identification of additional data elements and cleanup of canned reports to better address the needs of users
  
- ❑ **Firm management harmonization with DUNS**
  - ❑ Coordination with the Firm Management team and Dun & Bradstreet to harmonize our firm inventory with the DUNS Number to support a unique identifier for each firm in FDA's inventory
  
- ❑ **Remote Training**
  - ❑ Develop video modules for using various systems (ex. ER, OASIS, ITACS)



# ORA HQ Realignment

## Office of Regulatory Affairs Effective October 1, 2012



Operational units shaded green are new or have been modified

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# PREDICT & ITACS



## IMPORTS

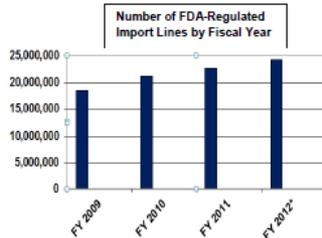
### PREDICT FACT SHEET

**PREDICT** (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting) is the FDA's electronic screening tool for import operations that replaces the legacy screening tool in OASIS (Operational and Administrative System for Import Support). It works behind the scenes to screen all lines of imported product electronically submitted to the FDA via the US Customs and Border Protection interface.

**MARCS** (Mission Accomplishment and Regulatory Compliance Services) Imports Entry Review is FDA's new application used to make initial admissibility decisions, assign field work, and display the results of the PREDICT risk-based screening and database lookups.

National rollout of PREDICT began in September of 2009 to all 16 import Districts and was completed in December 2011.

PREDICT is designed to calculate a customized risk score for every line in an entry. Score calculations are based on numerical weights assigned to inherent risk rules, data anomaly rules, data quality rules, and the compliance history of firms (ex. manufacturer, shipper, and consignee) and product associated with the line.



The application of rules results in the generation of a cumulative score for a specific line. The rules can generate negative increments (good credit), neutral (no increment change), or positive increments (increased bad risk). The higher the cumulative score, the greater the identified risk.

Each line receives a percentile rank based on all other lines screened over the past 30 days. The risk rank is designed to focus FDA's limited resources using a risk-based approach.

Rules addressing a FDA field assignment, an Import Alert, an Import Bulletin, or District/Center requested criteria are explicitly flagged to be manually reviewed and have no impact in the calculation of the score.

PREDICT's automated database lookups link to data stored in Center databases, such as a firm's registration

and product listing and approval status. The results of these lookups are presented to the FDA staff in the PREDICT mashup to more efficiently review the compliance status of applicable firms and products.

Open source intelligence validated by FDA staff is used to develop rules to proactively target issues that may potentially impact public health.

Complete and accurate data transmitted allows FDA to more efficiently and effectively make admissibility decisions by holding higher risk products for review and examination while allowing lower risk products to enter domestic commerce without further FDA review.



## IMPORTS

### ITACS FACT SHEET

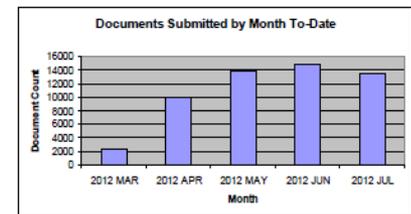
**ITACS** (Import Trade Auxiliary Communication System) provides the Import Trade Community with three functions: the ability to check the status of FDA-regulated entries and lines, the ability the submit entry documentation electronically, and the ability to electronically submit the location of goods availability for those lines targeted for FDA exam.

Note that currently only open entries may be queried in ITACS. Those entries that have been completely released are considered closed and cannot be queried at this time. Additionally, the status of truck and air shipments will only be displayed after FDA has received electronic notification that the shipment's conveyance has been arrived by Customs and Border Protection (CBP).

Documents may currently be submitted as PDF files, but planned future functionality will allow for submission of additional document types.

When submitting availability of goods for examination, the user may either indicate that the goods are located at the consignee as filed in the FDA entry, or at another location as entered by the user.

ITACS offers several benefits to the Import Trade Community as well as to



FDA. The ability to check the status of entries reduces the need for phone calls inquiring about status, which saves time for both FDA staff and trade. The ability to submit documents electronically reduces the dependence on traditional means such as fax and courier delivery, as well as lowering the chances of documents being lost. Electronic submission of goods availability reduces the need for faxes and phone calls to deliver this information.

ITACS may be accessed at <https://itacs.fda.gov>. At this time, no login accounts are necessary. All that is needed is a valid Customs entry number that has been successfully transmitted to FDA. In the future, login accounts are planned in order to enable the electronic distribution of Notices of FDA Action as well as to allow two-way communication between Trade and FDA.

Additional planned future functionality will include the ability to query FDA firm identifiers and product codes, as well as the display of laboratory timeframes for those lines which FDA has sampled.

For questions about ITACS as well as to report problems and suggest improvements, please contact us at [itacsupport@fda.hhs.gov](mailto:itacsupport@fda.hhs.gov).

#### Highlights of Future Functionality

- Login capabilities
- Notices of FDA Action
- Link to laboratory timeframes
- Additional document types
- Ability to query closed entries
- Printer-friendly version of status page

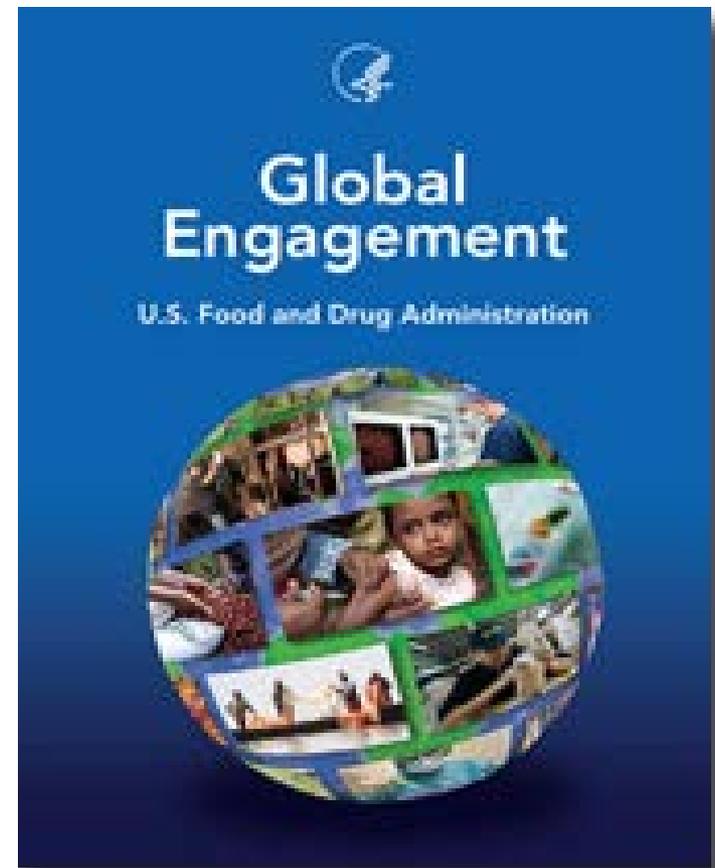
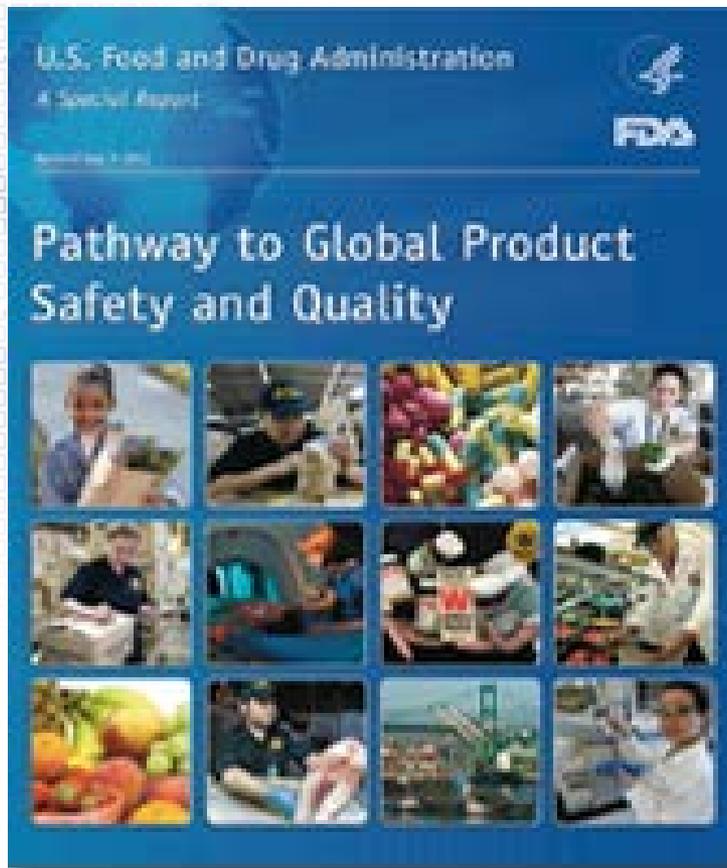




# The Pathway to Global Product Safety & Quality



<http://www.fda.gov/AboutFDA/GlobalInitiative/default.htm#GEReport>





**Thank you**

**Questions?**



U.S. Department of Health and Human Services

**Food and Drug Administration**