US Food and Drug Administration

FDA Presentation on Import Process
And Other Current News
January 12, 2010

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Los Angeles District Office

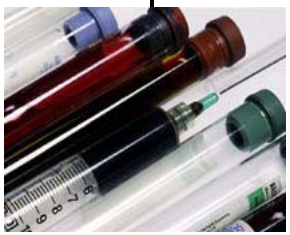
FDA Organization

Office of the
Commissioner

Office of Regulatory Affairs

Center for
Food
Safety &
Applied
Nutrition

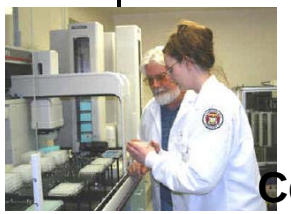
Center for
Drug
Evaluation &
Research



Center for
Biologics
Evaluation &
Research

Center for
Devices &
Radiological
Health

Center for
Veterinary
Medicine



National
Center for
Toxicological
Research

Center for
Tobacco
Products

Products FDA regulates

Human foods (with the exception of most meat and poultry)

Drugs (both human and animal)

Animal feeds

Biologics

Cosmetics

Medical devices

Electronic products that emit radiation

Tobacco Products

Center for Tobacco Products
CTP

Overview of the Family Smoking Prevention and Tobacco Control Act

President Barack Obama, June 22, 2009, signing the Family Smoking Prevention and Tobacco Control Act

"This legislation is a victory for bipartisanship, and it was passed overwhelmingly in both Houses of Congress. It's a victory for health care reform, as it will reduce some of the billions we spend on tobacco-related health care costs in this country. It's a law that will reduce the number of American children who pick up a cigarette and become adult smokers. And most importantly, it is a law that will save American lives and make Americans healthier."

What is this New Law?

- Public health and the Family Smoking Prevention and Tobacco Control Act (FSPTCA)

- This law gives FDA authority over tobacco products by adding a new chapter to the Food, Drug and Cosmetic Act for tobacco products and reinstating the 1996 final rule.
- The law gives FDA the authority to regulate tobacco products and manufacturers.

Public Health and FSPTCA

- Passage of the FSPTCA is a significant new component of the larger goal of tobacco control
- FSPTCA established a new standard for FDA: to regulate tobacco products based on a public health and population health standard

FDA Tobacco Control Goals

- Prevent youth tobacco use
- Help adults who use tobacco to quit
- Promote public understanding of contents and consequences of use of tobacco products
- Develop science base and begin meaningful product regulation to reduce the toll of tobacco-related disease, disability, and death

Public Health Tools Established Under FSPTCA

- Ban of flavored cigarettes
- Tobacco Products Scientific Advisory Committee (TSPAC)
- Registration and listing
- Ingredient submissions to FDA
- Advertising standards and warning labels
- Tobacco product standards
- Enforcement authority

Intra-HHS Coordination

- Assistant Secretary for Health
- CDC: Surveillance, epidemiology, product analysis
  - Office on Smoking and Health
  - National Center for Environmental Health
- SAMHSA: Tobacco outreach and surveillance
- NIH: Tobacco Research Topics

State and Local Involvement & Coordination

- FDA bridge to state tobacco control programs
- The tobacco control efforts in place in states and localities are crucial
- FDA will seek opportunities to support state activities related to the FSPTCA

Office of Regulatory Affairs (ORA)

ORA is the lead office for all field activities of the Food and Drug Administration

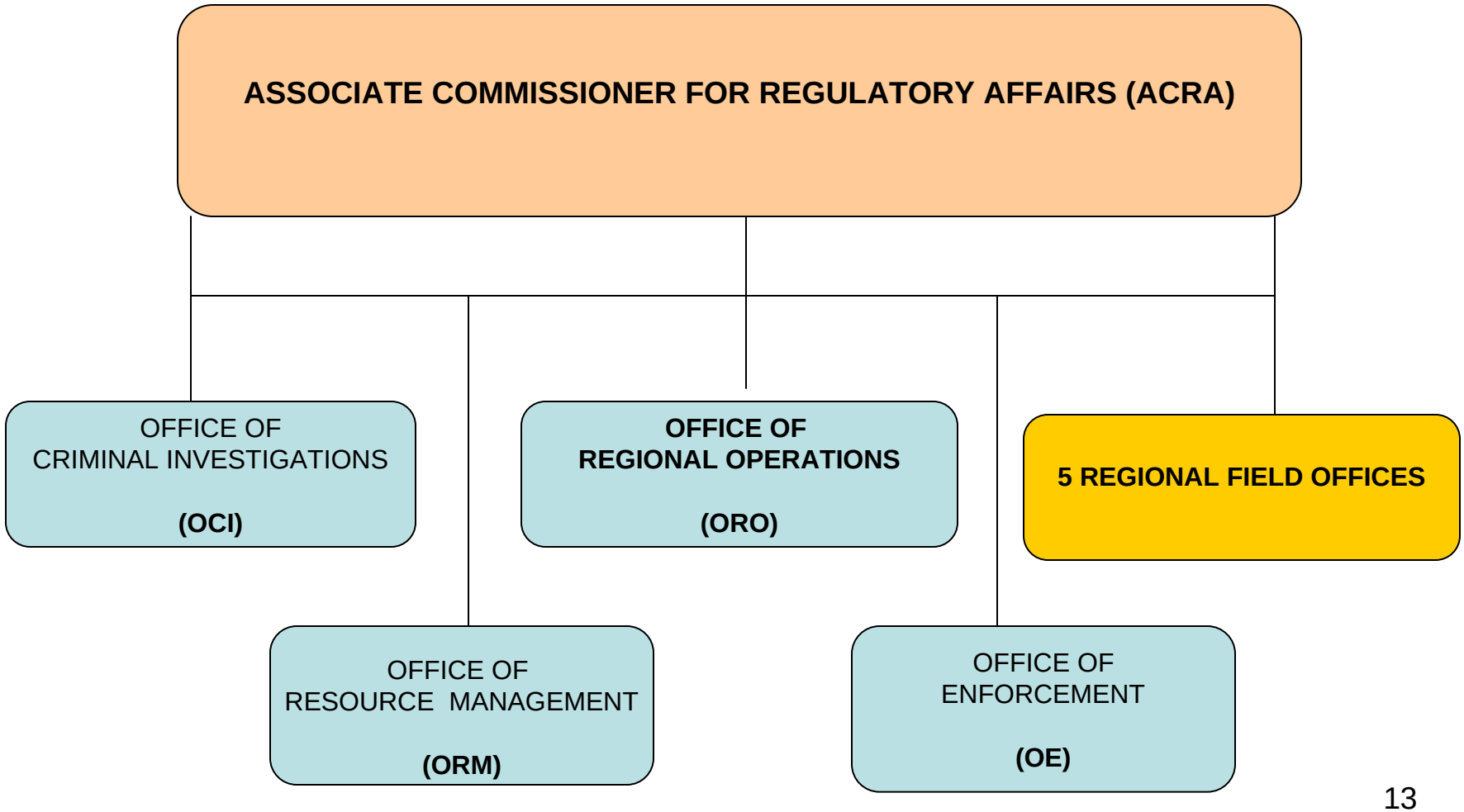
Field offices report to the Associate Commissioner for Regulatory Affairs (ACRA)

ORA Web Site:
www.fda.gov/ora/hier/ora_overview.html

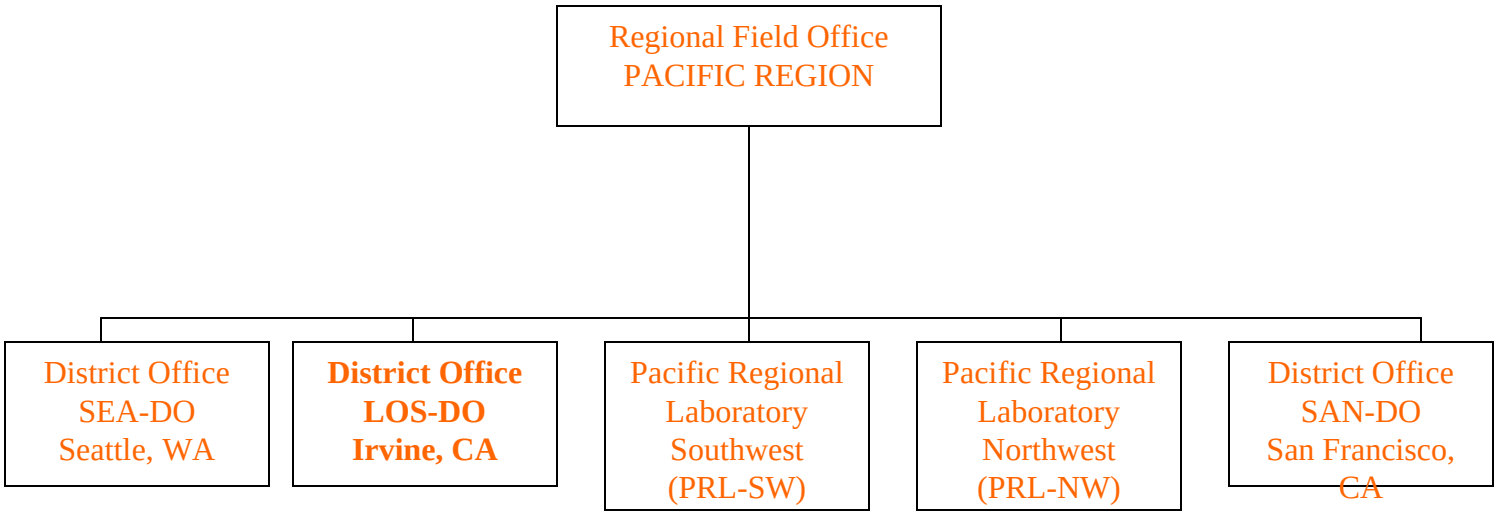
Field force of approximately 1400 investigators and inspectors.

FDA @ Irvine

Office of Regulatory Affairs (ORA)



FDA Regional Field Office – Pacific Region



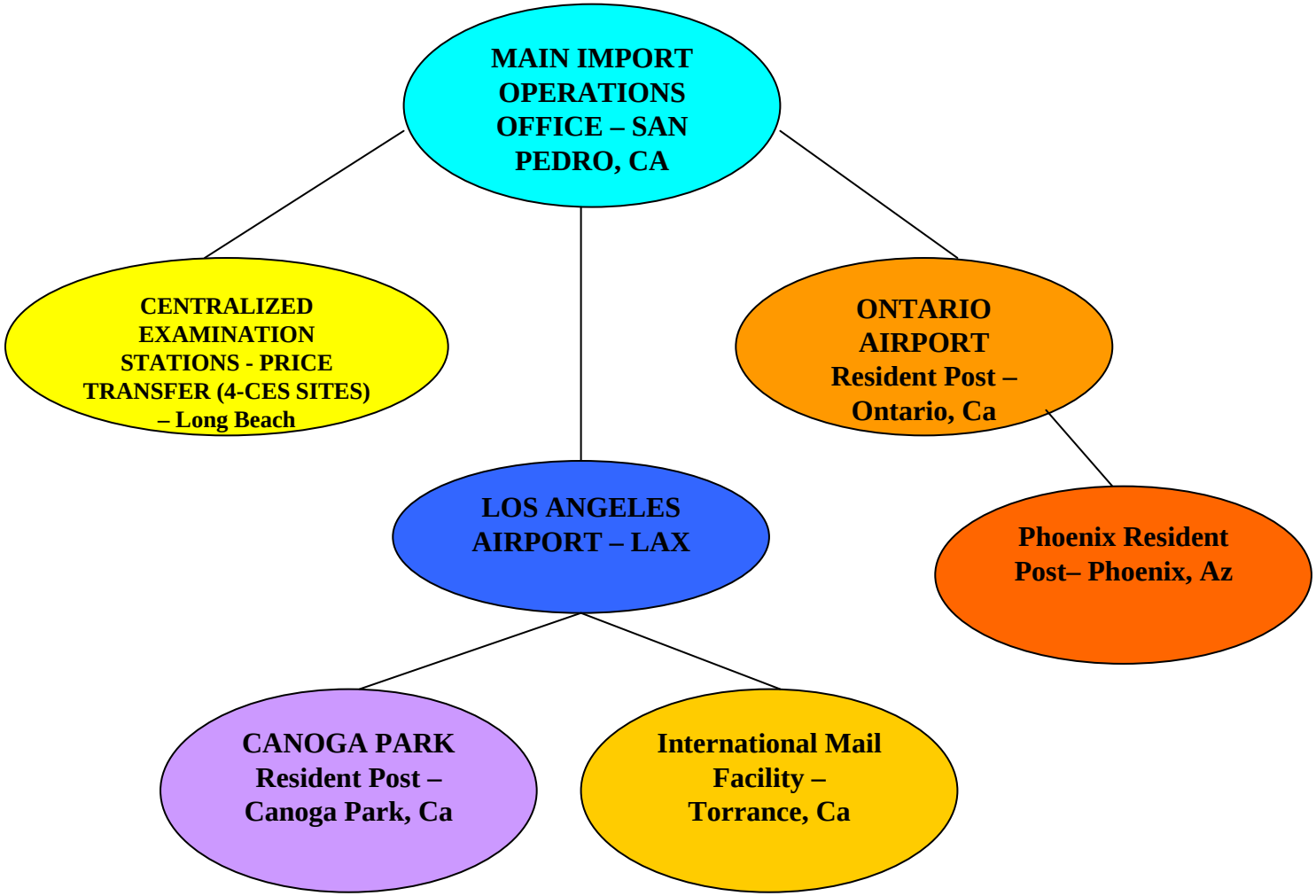
LOS ANGELES IMPORT OPERATION

Southern California

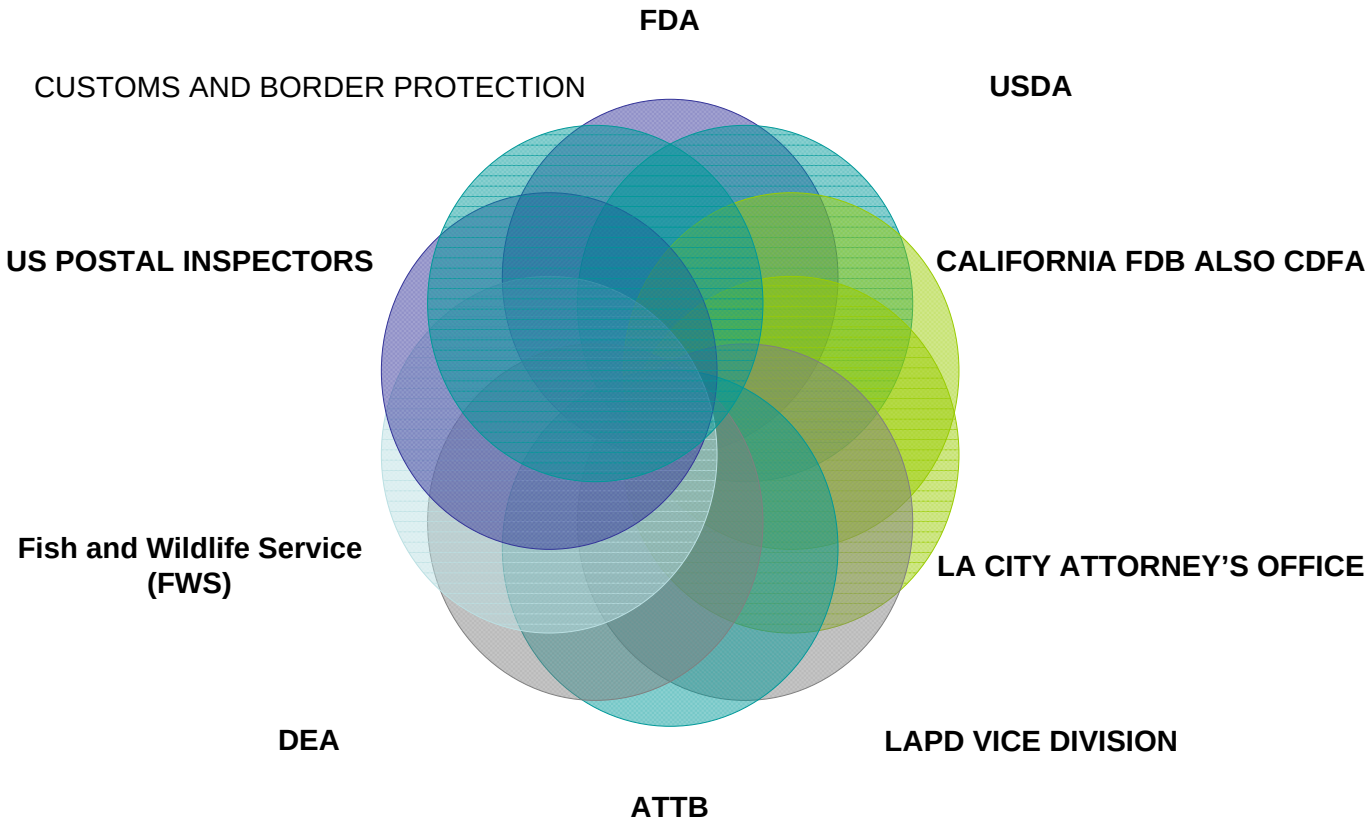
- Port of Los Angeles/Long Beach
- Airports – LAX, Ontario

#1 in volume for U.S., #5 in world

FDA LOS-DO IMPORT OPERATIONS



OGA Relationships



SHARE THE SAME COMMON GOAL: PROTECT PUBLIC HEALTH

Imports are Critical to ORA's Mission

Protecting consumers and enhancing public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products.

- Inspections
  - Pre approval
  - Post market
- Investigations
  - Consumer Complaints
  - Emergency Response
- Sample Collection and Analysis
- Import Product Review
  - Field Exams
  - Sampling

Changes and Challenges

IT Systems and Modes of Outreach

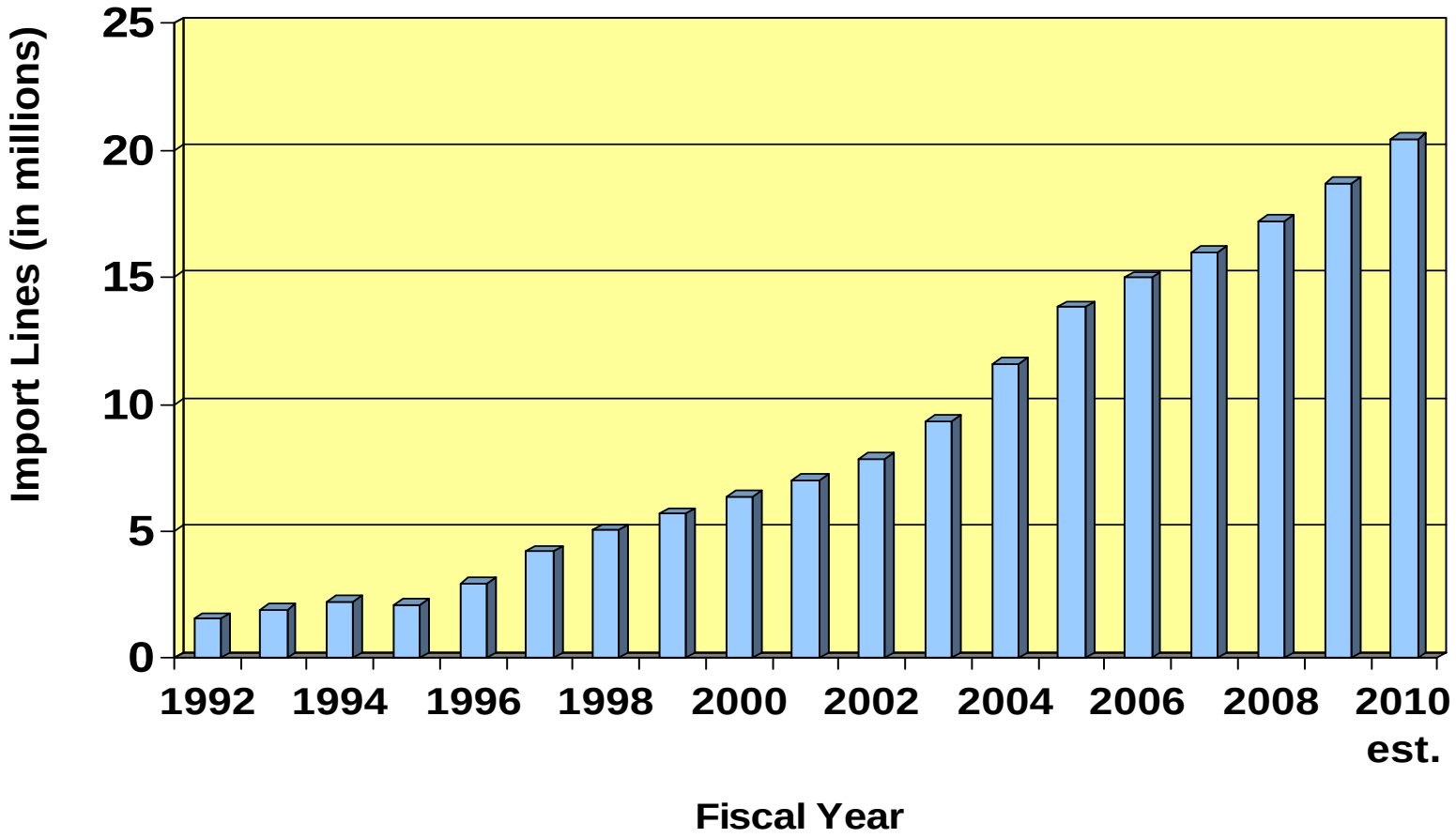
- Outdated FDA data handling capacity.
  - Growing imports
  - Need for integrated systems
- Information to protect consumers difficult to deliver.
  - Consumer level
  - Retail level
- IT Infrastructure is Outdated and Needs To be Updated to Handle Import Capacity.

Continual Challenge

- Volume of Imports!

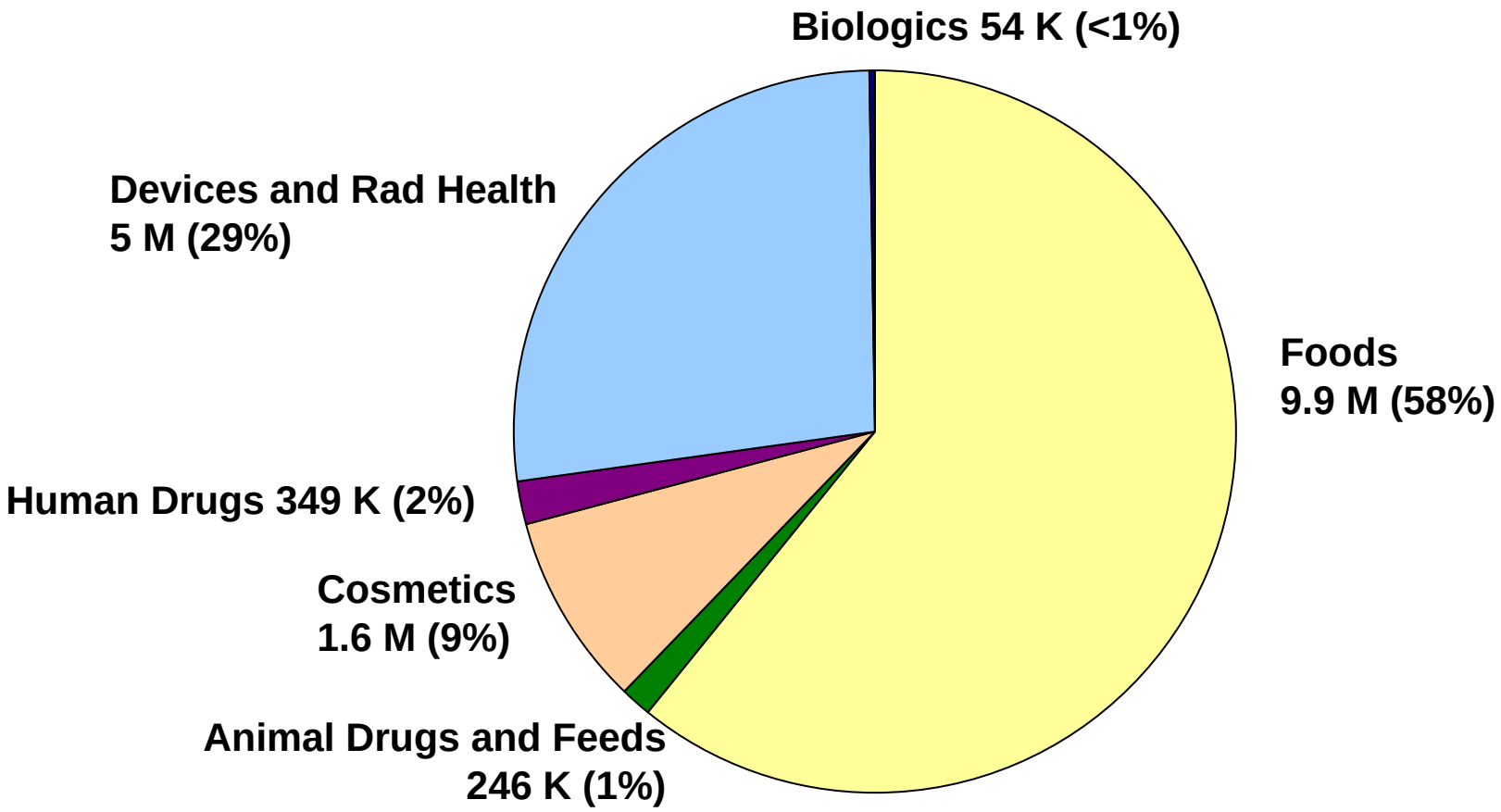
Import Volume History

17.2M Lines Actual for FY2008
18.7M Lines Estimated for FY2009
20.5M Lines Estimated for FY2010



FDA Statistics

- Current data indicates that FDA will process 18 Million Lines this fiscal year



Challenges

Imported Food in the United States

- **15-20% of U.S. food supply is imported.**
- 24-35% of produce is imported
- 45% of fresh fruits are imported.
- Imports of seafood rose from less than 50% of U.S. seafood consumption in 1980 to more than 75% today.
- FDA Los Angeles District handles around 15% or the nation's Food related items.

Challenges: Import Safety

- Population at high risk is growing
- Consumers demand safe products regardless of origin
- Recent product problems-heparin, melamine, *Salmonella* - point to vulnerability
- Consumer groups, Media, Congress demand imported goods are safe!

Need Science Based Evaluation and Risk Targeting

- Focus on risks over a Product's life cycle –
- Target resources to:
  - Gather the science
  - Rank products based on risk
  - Focus prevention and intervention

- System enhancements: PREDICT and ITACS

The Import Process

– Electronic entries received via a Customs and Border Protection (CBP) interface with FDA (ACS/OASIS Interface)

- ABI – Automated Broker Interface (Filer to ACS)
- ACS – Automated Commercial System to OASIS

– Entries input manually by FDA field staff

- Informal or Non-ABI entries
- Mail
- Baggage

Note - 99+% of FDA eligible entries are transmitted via ABI

Import Operations Overview

Federal Food Drug and Cosmetic Act
Section 801(a)

- Administrative decision to detain a product based on the analysis of a sample or otherwise.
- Article refused if it **appears** it has been manufactured, processed, or packed under insanitary conditions or otherwise adulterated or misbranded
- 'Appearance' standard for imported articles

Import Operations Overview

Entry Filer/Importer

↓

US Customs

↓

FDA Prior Notice Center (Foods)

↓

FDA Entry Reviewer →

- Investigator inspects, samples shipment
- Lab analysis conducted on samples
- Entry documents reviewed

FDA Compliance Officer ↑

↓

Release

Import Operations Overview

Lab analytical sheet

Investigator's report

Entry reviewer's recommendation

Compliance Officer

- **Release** – goods may be delivered into US commerce
- **Investigative Follow-up**
- **Detain** – hearing period
- **Recondition** – goods brought into compliance
- **Refuse** - goods exported or destroyed

Import Operations Overview

Current FDA enforcement and administrative tools

- Detention/Refusal
- Import Alerts
- Regulatory letters e.g. warning letters
- Product seizure
- Injunction
- Recall
- Criminal Prosecution

IMPORT PROCESS

- Importer or agent files entry documents with Customs
- FDA Reviews documents which include CBP 3461, invoice, bill of lading, packing list, etc.
- FDA makes a determination on the admissibility of the product based on FDA regulation (FDA District would make decision for entries submitted for district ports.)
- http://www.foodsafety.gov/~lrd/import.html
  (Good resource on FDA Import Procedures)

FDA ENTRY REVIEW

- FDA Review Entry Documents to determine if a physical examination is needed.

  Provide the following information (help speed up the entry review process)

  - LACF – Low Acid Can Food (SID/FCE information)
    (Make sure to provide can dimension for every size can)
  - Drug Affirmation of Compliance
  - Device Affirmation of Compliance
  - Accession Number (RadHealth Product)
  - MOU information

FDA FIELD EXAMINATION

- FDA Sends an Notice of FDA Action to the Importer of Record, Consignee, and the Filer

- The Importer of Record or Filer will need to submit a location letter to FDA that should include the following information:

- Entry #
- Name and address where product is held.
- Dates when the entry is available for field examination.
- Point of Contact (Name and Phone Number)

FDA FIELD EXAMINATION

- The Notice of FDA Action indicates which items are "Pending FDA Review".

- Make sure that the products that are under "Pending FDA Review" status are held intact and have not been distributed until a written notice or an additional message has been received by FDA.

- FDA Investigators will determine if a sample collection is needed base on:
  - Nature of the product
  - FDA priorities
  - Past history of the commodity

FDA SAMPLE COLLECTION

- Once samples have been collected by FDA Investigators, they are sent to an FDA lab for analysis.

- An Notice of FDA Action is generated and sent to the Importer and filer indicating which products have been sampled.

FDA Sample Collection, cont.

- When the sampled products are still pending FDA Lab analysis, it is important that the product is still held intact and have not been distributed until FDA makes a final determination on the admissibility of the products.

- If the sample was determined to be in compliance with FDA requirements, FDA sends a Release Notice to the importer and filer.

FDA DETENTION

- If FDA detained a product, then an Notice of FDA Action is generated explaining the reason behind the detention.
- Follow the instructions on the notice and pay attention to the timeframe for response.
- You can contact the compliance status line for additional information regarding the detention.

Notice of FDA Actions

- Notice of FDA Action specifying the article was refused
- Notice of Detention
- Notice of Sampling
- Notice that product “May Proceed”

The data filers enter are critical

CONTACT INFORMATION

- **Compliance Status – 310-971-2399 (Handles status related to detention, refusal, compliance extension, Compliance status after sampling, and reconditioning)**
- **General Status – Goes directly to the FDA Supervisors who are divided among commodities/operations. They handle questions involving (locations, field examination assignments, and entry document status) (310) 971-2280**
- **General email address: LAIMPORTS@fda.hhs.gov**

NEW!: Improving Import Communication and Screening

- PREDICT—Predictive Risk-Based Evaluation for Dynamic Import Compliance and Targeting
  - Entry data quality, and why it <u>really</u> will matter with PREDICT
- ITACS—Import Trade Auxiliary Communication System

System Enhancements and Development

- **PREDICT**

  FDA has developed a powerful tool that will enhance its ability to more fully utilize import screening resources and more effectively target shipments for detention or further testing*
- FDA has been communicating the roll out of these New Applications through various Outreach Events.

*McKinsey and Associates

PREDICT

Purpose: Improve import screening and targeting to

- Prevent the entry of adulterated, misbranded, or otherwise violative goods
- Expedite the entry of non-violative goods

Method: Replace the admissibility screening portion of FDA's legacy electronic system for processing import entries.

OASIS

Operational and Administrative System for Import Support

- Legacy system operating 24/7 FDA-wide since 1998
- The only system in the Federal government which exchanges import admissibility data with U.S. Customs & Border Protection in real time
- Provides --
  - Electronic screening of entry lines
  - Workflow management for entry reviewers, inspectors, and compliance officers
  - Generation of notices regarding admissibility decisions

PREDICT method

- Use automated data mining and pattern discovery
- Utilize open-source intelligence
- Provide automated queries of Center databases where relevant (i.e., registration and listing, marketing approval status, low-acid canned food scheduled processes, etc.)

PREDICT method

- Improve the targeting of entry lines by –
  - Scoring each entry line on the basis of various factors
  - Increase the number of automated, real-time, "may proceed" decisions, thereby giving entry reviewers more time to evaluate higher-risk lines
  - For those lines not given an automated "may proceed," providing reviewers with the line scores and the reasons for those scores.

Examples of source data for PREDICT screening rules

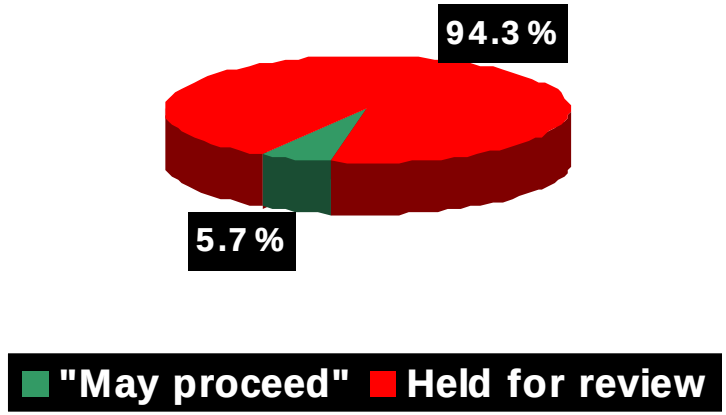
- Results of field exams and sample analyses of previous entries
- Results of facility inspections, foreign and domestic
- Ratings of inherent product risks
- Accuracy of product and facility coding by entry filers and importers

Examples of source data for PREDICT screening rules

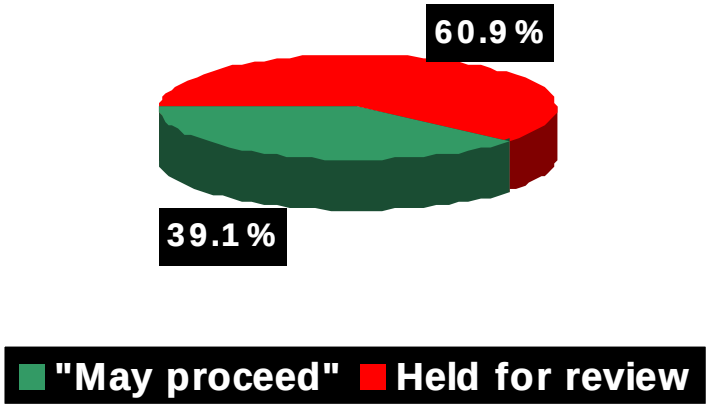
- Data anomalies within the current entry
- Admissibility history with respect to the manufacturer, exporter, importer, and consignee for the current product (at industry and more specific levels)
- Open source intelligence pertaining to the manufacturer, foreign locale, product, etc.

Effective rates – Automated “may proceed”

FY 2006 Control



PREDICT



The effective rate is lower than the individual line rate because of a business rule which requires that if any one line of an entry does not receive a “may proceed,” all lines will be held.

Accurate, consistent, complete data

- To expedite entry screening by PREDICT, importers and entry filers must provide:
  - Consistent, accurate identifiers for firms
  - Accurate product codes
  - All of the relevant affirmations of compliance
- With those data PREDICT will be able to issue system 'may proceeds' quickly for lines with lower targeting scores
- OASIS tracks FDA corrections of data submission errors, and PREDICT uses these data to adjust the targeting scores for future entry lines

Affirmations of compliance

- Affirmations of compliance are data elements submitted voluntarily to FDA to expedite the entry review process. For example:
  - New drug application number
  - Device “510(k) clearance” number
  - National drug code (NDC)
  - Radiological health product report accession number

With PREDICT:

Affirmations of compliance

- With <u>accurate and complete</u> affirmations of compliance (NDA, ANDA, PMA, 510(k), NDC numbers, etc.), PREDICT can do the automated lookups for marketing status.

- If an automated lookup fails, the entry line will be forwarded to a reviewer for manual processing.

Acidified and low acid canned foods (ALACFs and LACFs)

- **FCE: Food canning establishment number**

  This is typically a 5 digit number assigned by FDA

- **SID: Scheduled process identifier number**

  YYYYMMDDSSS (11 digits) where:

YYYY	represents the calendar year
MM	represents the month (e.g., 02 for February, 10 for October)
DD	represents the day of the month (e.g., 02, 19, 30, etc.)
SSS	represents a unique sequence number to identify each process submitted to FDA by the manufacturer on the same date

Acidified and low acid canned foods (ALACFs and LACFs)

- Use the importer's text description field to supplement the product code description when necessary, for example, to indicate packing media (oil, brine, tomato sauce, etc.) and/or product style (sliced, chopped, etc.), and/or when there is no product code product name that matches the SID food name.

- See the following web pages for further information:
  http://www.fda.gov/Food/FoodSafety

5 of 5

Importers and Filers

- With PREDICT, the quality of the data you submit to FDA will count more than ever.
- Importers need to work closely with filers to ensure data quality.
- Poor data quality or missing data will increase the targeting scores for your subsequent entry lines (importers and filers).
- Higher targeting scores increase the likelihood of examination and/or sampling by FDA.
- Data error rates will be available to the public through the Freedom of Information Act.
- PREDICT has been rolled out since Sept 2009 in FDA Los Angeles Districts Office under the Enterprise IT Application known as MARCS (formerly OASIS).

Entry reviewer workload

Entry lines not given a "may proceed" by PREDICT go to an entry reviewer for manual processing.

"In" box

ITACS – Purpose and Benefit

- Currently, the majority of phone calls from the Import Trade community relates to the status of a particular shipment.
- Communication with an FDA Investigator is sometimes difficult because they're typically out in the field.
- ITACS will allow another form of communication aside from phone, fax, letter, appointment or email.

PRIOR NOTICE

Go to http://www.fda.gov/

Choose “Prior Notice of Imported Food” link

- 866-521-2297 Available 24/7

How Do I Submit Prior Notice?

- All prior notice information must be in the English language using the Latin (Roman) alphabet, except:
  - individual's name, the name of a company, and the name of a street may be submitted in a foreign language

- Must be submitted electronically through:
  - CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS), or
  - FDA's PN System Interface (PNSI) at http://www.access.fda.gov

Dietary Supplement GMPs

- Final rule in 2007 governs preparation, packing, and holding of dietary supplements [402(g)(2)]
- Rule applies to all domestic and foreign companies that manufacture, package, label, or hold dietary supplements.
- A dietary supplement that does not comply with GMPs is adulterated under 402(g)(1).

Dietary Supplement GMPs

GMP requirements related to:

- Design and construction of physical plants to facilitate maintenance
- Cleaning
- Proper manufacturing operations
- Quality control procedures
- Testing final product or incoming and in- process materials (100% identity testing for incoming dietary ingredients)
- Handling consumer complaints
- Maintaining records

Dietary Supplement GMP Regulations

- Suppliers need to be “qualified” in order for certificates of analysis to be used by a dietary supplement manufacturer. The COA can be used to determine specifications for the product including heavy metals, pesticides, micro, and toxin levels.
- Dietary supplement manufacturers must do 100% identity testing. COA cannot be used to meet the 100% identity testing requirements.
- The ingredient supplier should work with the manufacturer to develop appropriate specification for the ingredient.

GMP Inspections

- Inspections began under Compliance Program 7321.008, Domestic and Import Dietary Supplements
- FDA has posted some EIRs
- Foreign inspections will be conducted to set up Import Alert for foreign DS manufacturers that are not in compliance with Part 111 GMP.

Identity Testing of Dietary Ingredients

- FDA established a petition process for exemption from the 100% identity testing requirement for dietary ingredients.
- Petition has to demonstrate that less than 100% identity testing does not materially diminish assurance that the dietary ingredient is the correct dietary ingredient.

GMP Ingredient Supplier Qualification

- Specifications must be met for all components.
- A firm can rely on a COA for non-dietary ingredients.
- A firm cannot rely on a COA from the dietary ingredient supplier unless it first qualifies that supplier through confirmatory testing.
- Firm must maintain documentation of qualification and records of audits.

FDAAA of 2007

- TITLE X – Food Safety
  - Section 1002 – Ensuring the Safety of Pet Food
  - Section 1003 – Ensuring Efficient and Effective Communications During a Recall
  - Section 1004 – State and Federal Cooperation
  - **Section 1005 – Reportable Food Registry**
  - Section 1006 – Enhanced Aquaculture and Seafood Inspection
  - Section 1007 – Consultation Regarding Genetically Engineered Seafood Products
  - Section 1009 – Annual Report To Congress
  - Section 1010 – Publication of Annual Reports

FDAAA §1005 Reportable Food Registry

Reportable Food Registry (RFR)

- Establish a Reportable Food Registry, to which instances of reportable food may be submitted via an electronic portal and a unique number issued to the person submitting the report upon receipt

FDAAA §1005 Reportable Food Registry

- "Reportable food" – an article of food (other than dietary supplements and infant formula), which has a reasonable probability of causing serious adverse health consequences or death to humans or animals

FDAAA §1005 Reportable Food Registry

- Requirement –Instances of reportable food should be submitted by:
  - A "responsible party," i.e., the individual who submits the food facility registration under section 415(a)), and
  - Voluntarily by Federal, State, and Local Public Health Officials

FDAAA §1005
Reportable Food Registry

FDA:

- Will establish an electronic portal to receive submissions
- Shall promptly review and assess information submitted to the Reportable Food Registry
- Will issue a unique identifier to the incident

FDAAA §1005
Reportable Food Registry

FDA:

Shall issue or cause to be issued an alert or notification with respect to a reportable food

as deemed necessary

after consultation with the responsible party

FDAAA §1005 Reportable Food Registry

FDA:

- Shall share information and coordinate efforts with the U.S. Department of Agriculture
- Shall share information and coordinate efforts with state and local public health and regulatory agencies

FDAAA §1005

Responsible Party:

- Must report as soon as practicable, but no later than 24 hours after a responsible party determines that an article of food is a reportable food
- Must submit a report through the electronic portal

FDAAA §1005
Reportable Food Registry

Responsible Party:

- Must investigate the cause of the reportable food if the reportable food may have originated with the responsible party
- Must submit initial information; followed by supplemental reports
- Must work with the FDA authorities to follow up as needed

FDAAA §1005
Reportable Food Registry

Responsible Party:

- May need to provide notification to immediate prior sources and immediate subsequent recipients of the article(s) of food
- Must maintain records of report submitted & any notifications made to FDA for 2 years

FDAAA §1005 Reportable Food Registry

What are the benefits of the RFR?

- Have focused actionable consumer messages
- Reduce consumer exposure to adulterated foods; reduce illness
- Improve consumer confidence in the food safety system

FDAAA §1005
Reportable Food Registry

RFR Home Page

www.fda.gov/ReportableFoodRegistry provides access to:

- RFR Guidance
- Reportable Food Registry At A Glance
- RFR Electronic Portal http://rfr.fda.gov
- Help Desk Support
- Technical FAQs

FDAAA §1005
Reportable Food Registry

SUPPORT — Two Help Desks

IT issues:

RFRTechSupport@fda.hhs.gov

Policy/Interpretation Questions:

RFRSupport@fda.hhs.gov

Leadership

Health and Human Services Secretary
Kathleen Sebelius

Leadership

FDA Commissioner Margaret Hamburg

Thank You For Your Attention

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Questions