



US FOOD and DRUG ADMINISTRATION



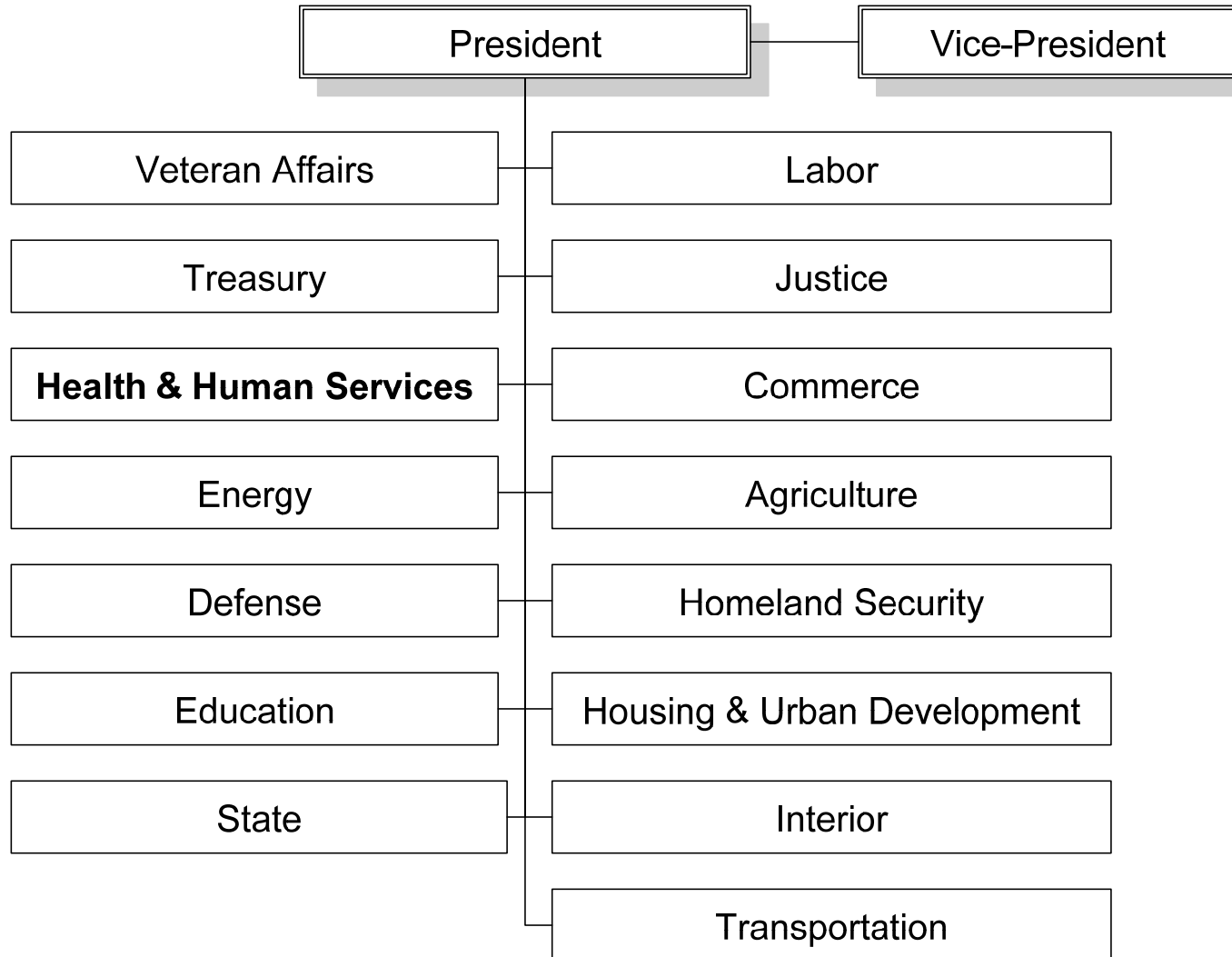
FDA Presentation on Los Angeles District
Import Operations

May 17, 2011

Dan Solis, *Director of Import Operations*
Los Angeles District Office

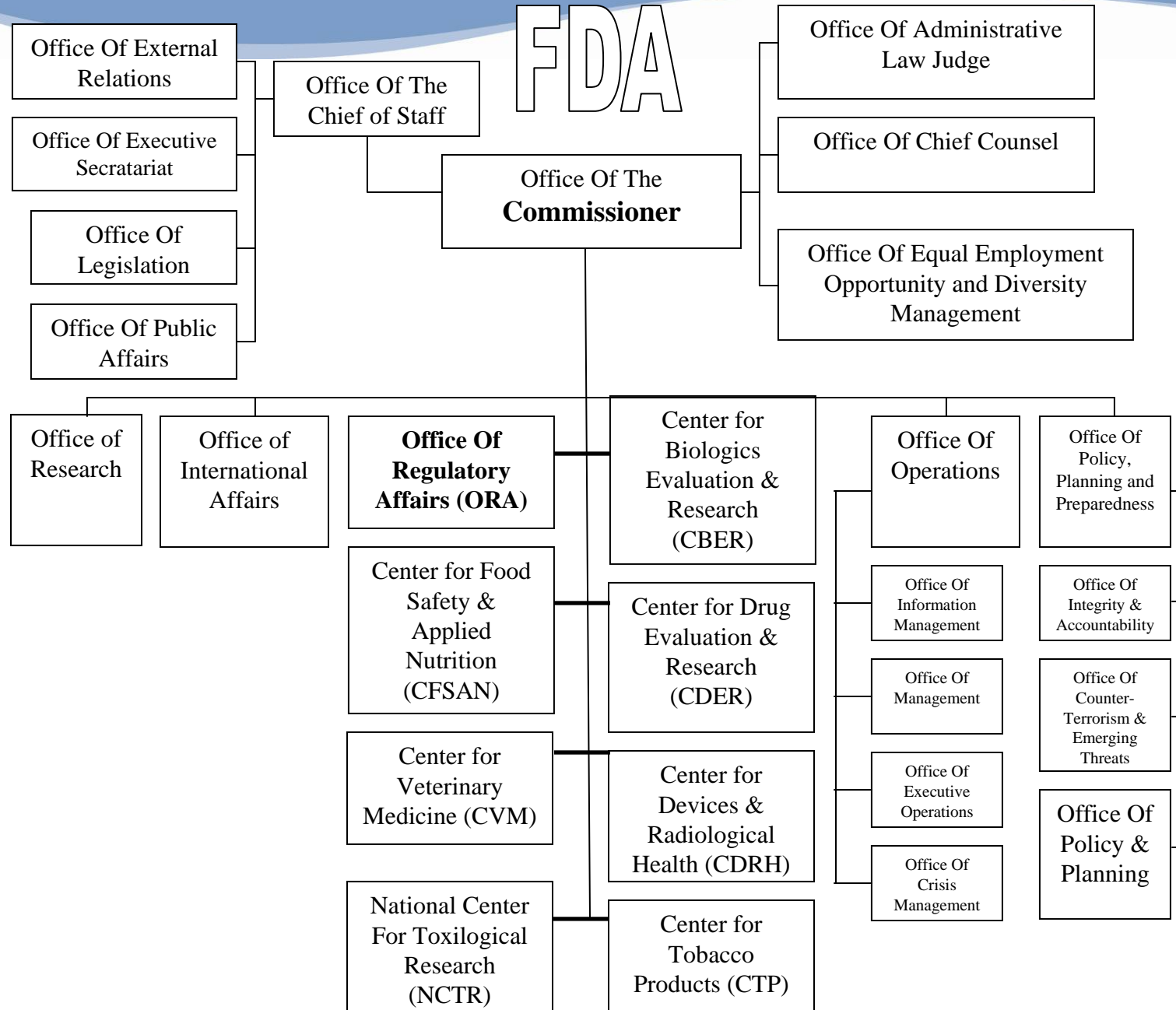


Cabinet of the United States





FDA ORGANIZATIONAL CHART





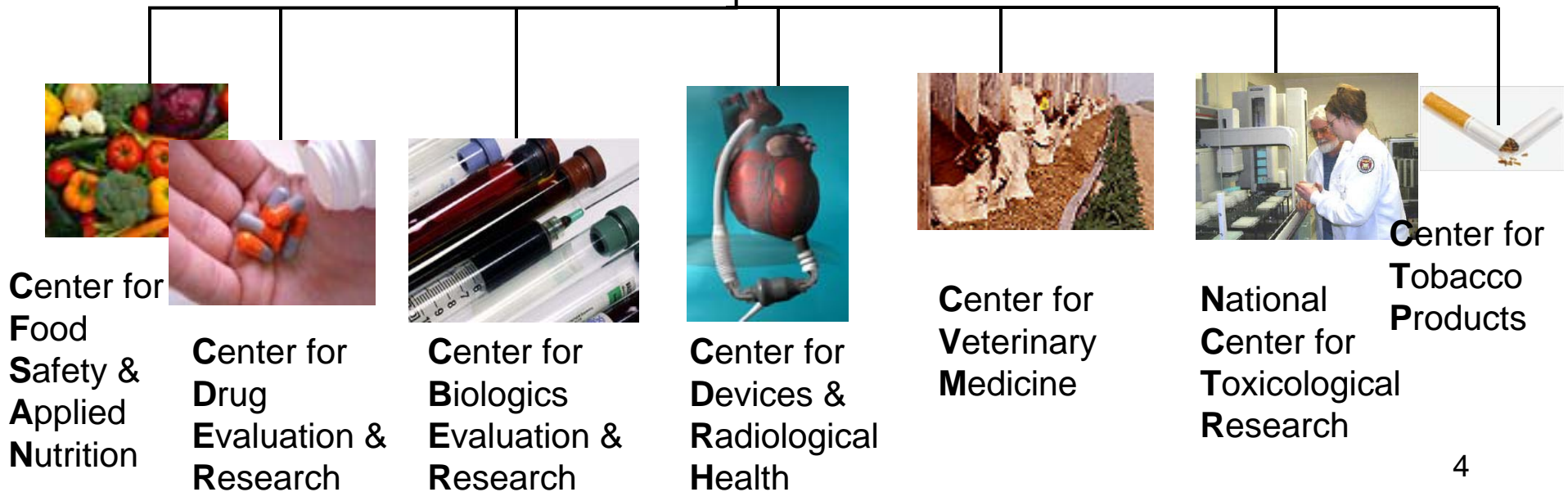
FDA Organization



Office of the
Commissioner

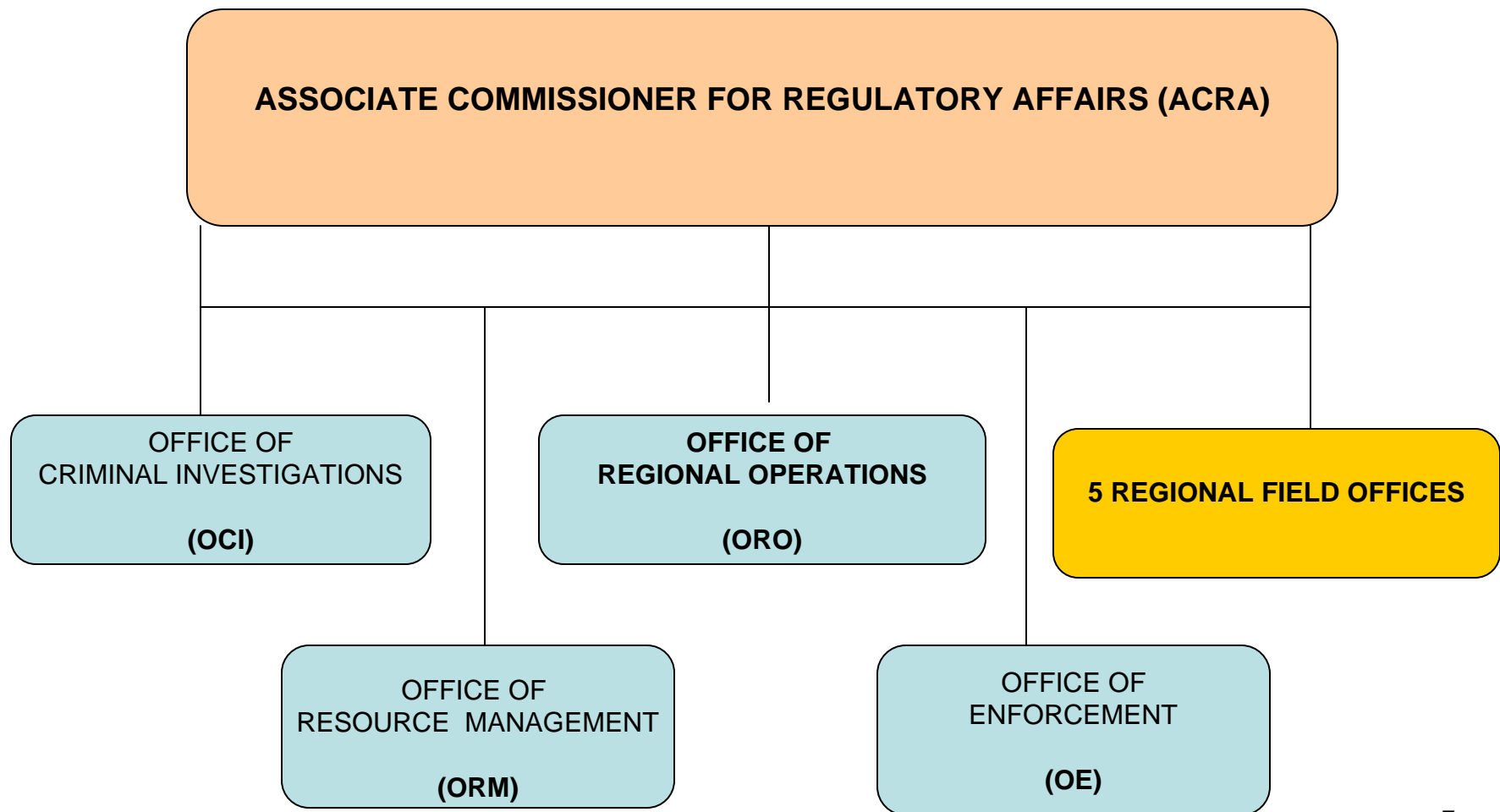


Office of
Regulatory
Affairs



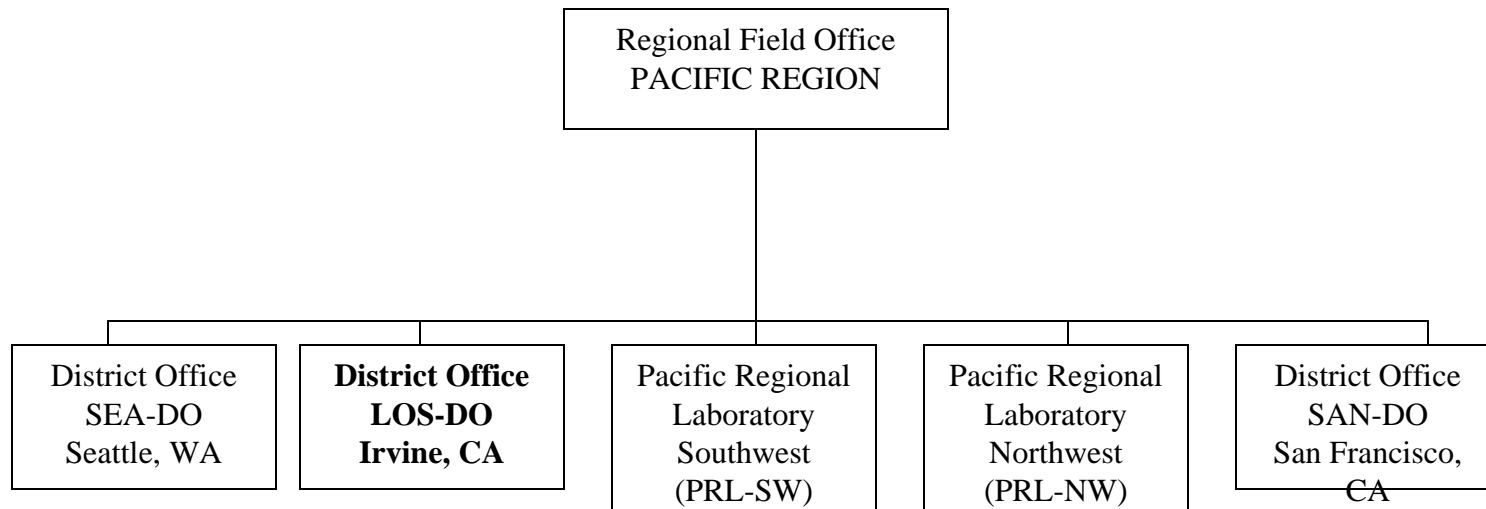


Office of Regulatory Affairs (ORA)





FDA Regional Field Office – Pacific Region

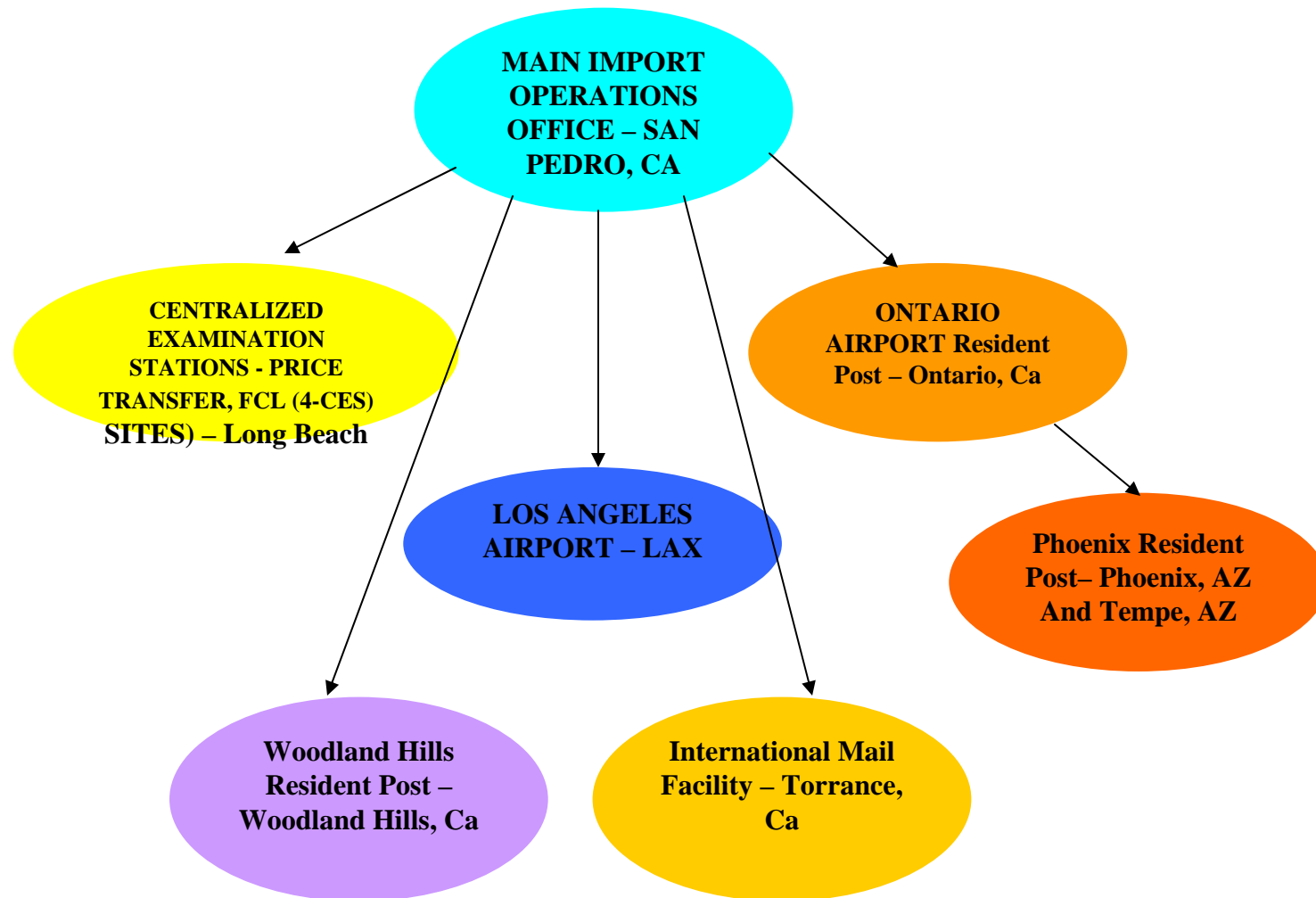




LOS ANGELES IMPORT OPERATIONS

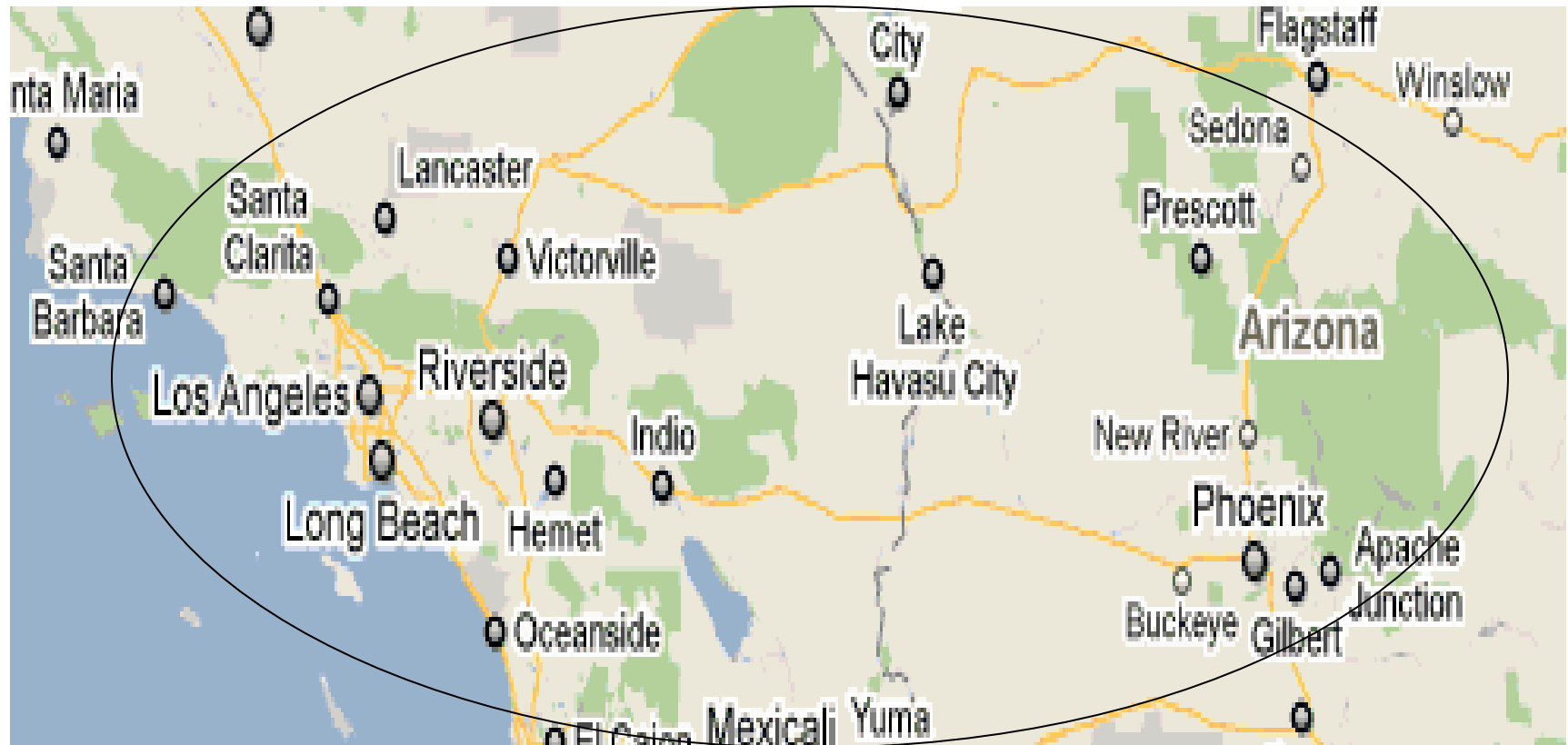


FDA LOS-DO IMPORT OPERATIONS





FDA LOS-DO IMPORT OPERATIONS





FDA Import Operation Mission

Prevention and Investigation of Adulterated and Misbranded FDA Products coming from Foreign Sources.

- Sample Collection and Analysis
- Import Product Review
 - Entry Review (PREDICT)
 - Field Exams
 - Sampling
 - Investigations
- Inspections
 - Establishment Inspections
- Investigations
 - Consumer Complaints
 - Emergency Response
- Recall



WHAT IS THE ROLE AND WHO WORKS FOR THE FDA LOS-DO IMPORT OPERATIONS?

- LOS-DO Imports is charged with reviewing, detaining, refusing preventing and investigating all FDA regulated product entries that comes into Southern California Seaports and Airports, with coverage from Port Hueneme to North of San Diego and as far East as Phoenix airport.
- A team of approximately 125 dedicated public health employees that includes nurses, pharmacist, chiropractors, chemist, microbiologist, PhD's, criminal investigators, lawyers, and scientists, with specialties ranging from engineering to pharmacology.



Continual Challenge

- Volume of Imports!



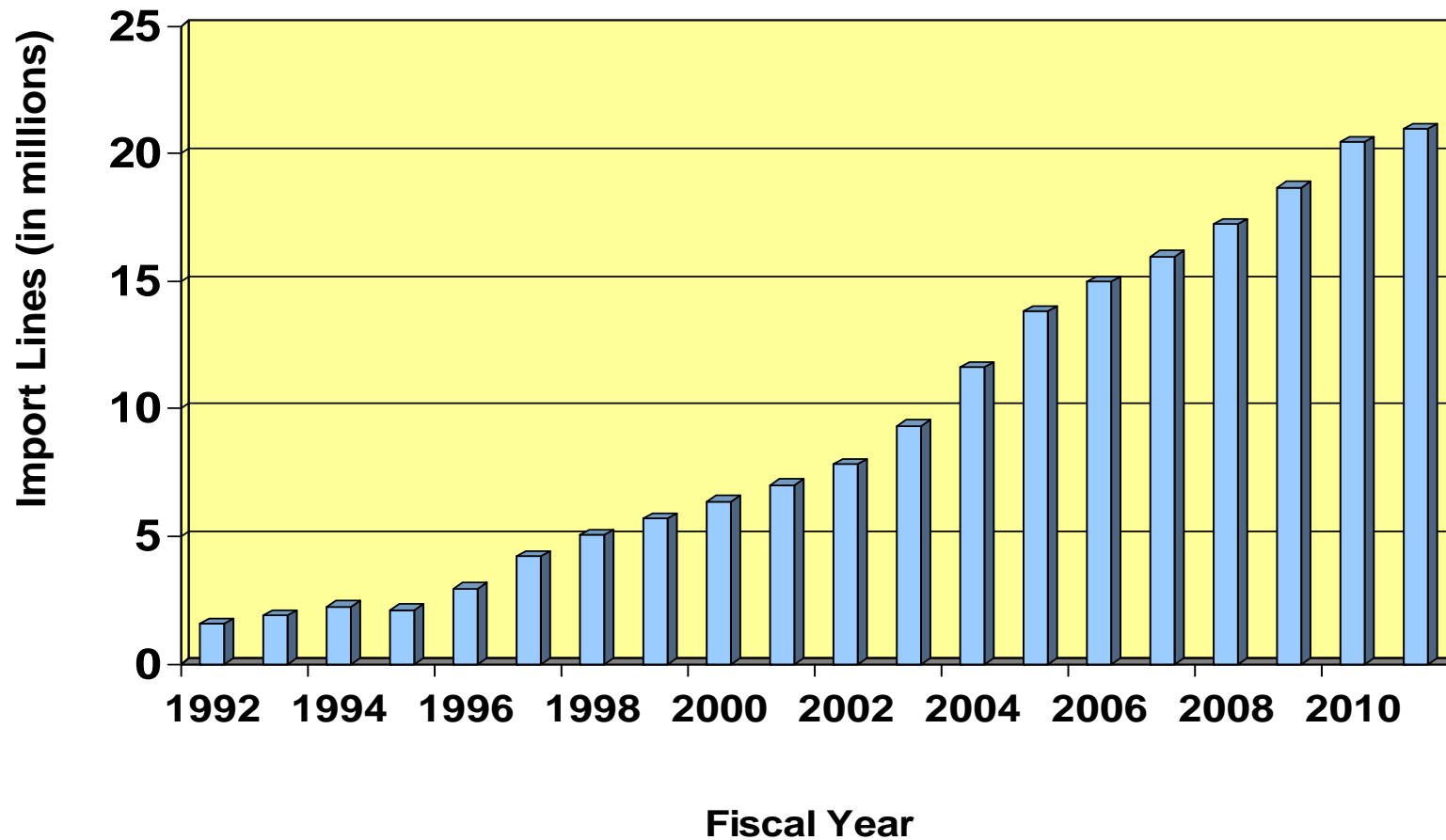


Import Volume History

18.7M Lines for FY2009

20.5M Lines for FY2010

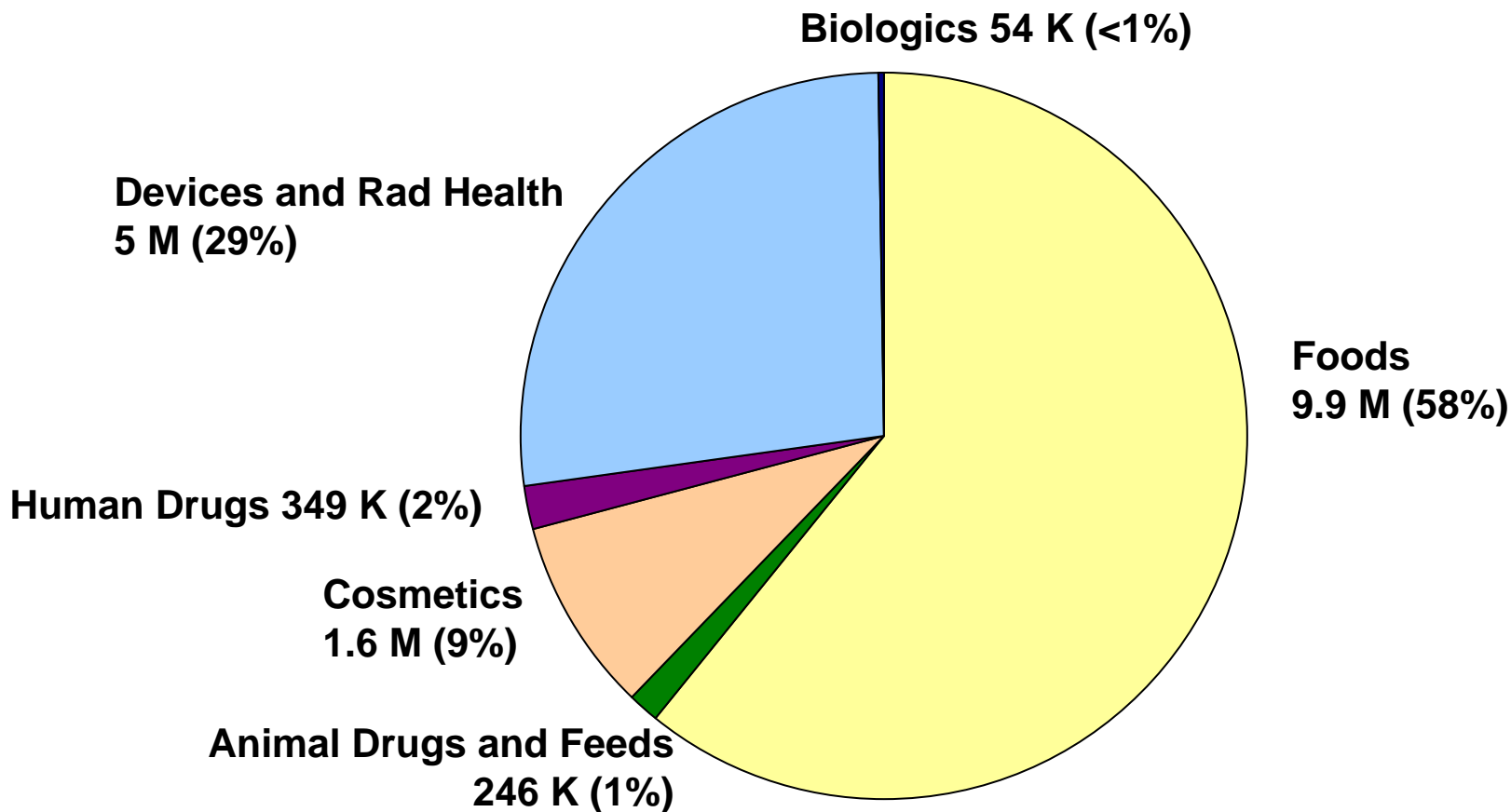
22 M Lines Estimated for FY2011





FDA Statistics

☞ Current data indicates that FDA will process 21 Million Lines last fiscal year





STATE OF IMPORT OPERATIONS AT LOS ANGELES PORTS

How to meet the challenges

- Increased resources
- Leveraging with OGA Partners
- New Laws and Regulations
- Access to Newer IT Technologies

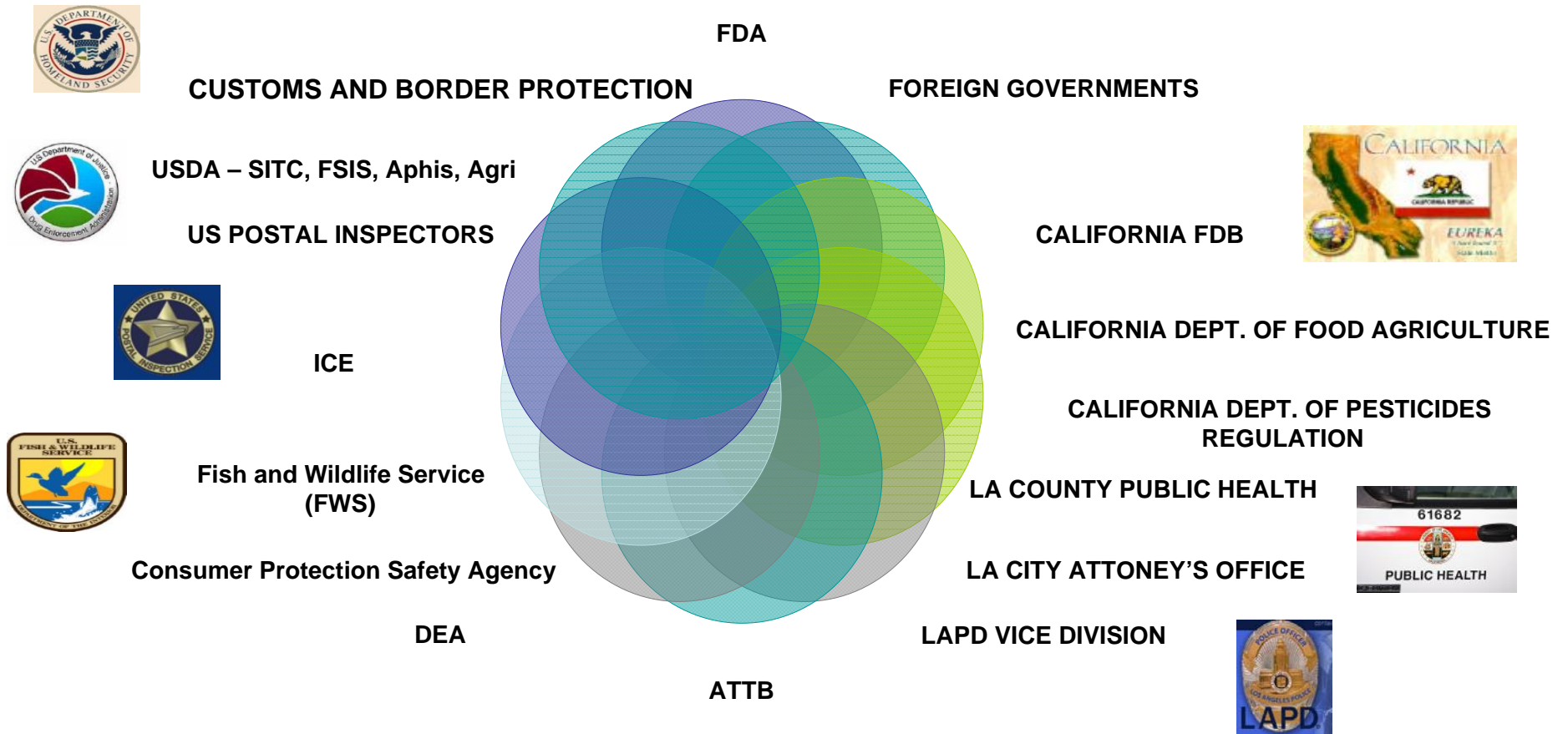


How to meet the challenges

- **Increased resources**
 - we have over 120 staff members
 - we have increased our Exportation/Destruction teams from 1 team to 5 teams which means we have over 50 investigators doing refusal entries follow ups.
 - we have increased our field operations investigators from 3 teams to 5 teams which means we have over 50 field investigators going to locations
 - we have an Seaport unit
 - we have a LAX unit
 - we have CES unit
 - we have an Ontario Airport unit
 - we have a Phoenix Az airport unit
 - we have a IMF unit
 - we have a Port Hueneme/Woodland Hills unit
 - we also now have an Entry Review \ PREDICT unit
 - I have also increased my Compliance Officer staff from 9 to now 12 Hearings Officers and have hired a Compliance Manager to run that department.



OGA Relationships



SHARE THE SAME COMMON GOAL: PROTECT PUBLIC HEALTH



LAWS ENFORCED BY THE FDA

- Federal Food, Drug and Cosmetic Act

Other Laws Affecting FDA:

Dates shown are when Public Law was first approved; laws may have been amended since original date

[Federal Food and Drugs Act of 1906](#) (repealed; for historical reference)

[Federal Meat Inspection Act](#) (March 4, 1907)

[Federal Trade Commission Act](#) (Sept. 26, 1914)

[Filled Milk Act](#) (March 4, 1923)

[Import Milk Act](#) (Feb. 15, 1927)

[Public Health Service Act](#) (July 1, 1944)

[Trademark Act of 1946](#) (July 5, 1946)

[Reorganization Plan 1 of 1953](#) (March 12, 1953)

[Poultry Products Inspection Act](#) (Aug. 28, 1957)

[Fair Packaging and Labeling Act](#) (Nov. 3, 1966)

[The National Environmental Policy Act of 1969](#) (Jan. 1, 1970)

[Controlled Substances Act](#) (Oct. 27, 1970)

Current regulations listing [schedules of controlled substances](#)

[Controlled Substances Import and Export Act](#) (Oct. 27, 1970)

[Egg Products Inspection Act](#) (Dec. 29, 1970)

[Lead-Based Paint Poisoning Prevention Act](#) (Jan. 13, 1971)

[Federal Advisory Committee Act](#) (Oct. 6, 1972)

[Government in the Sunshine Act](#) (Sept. 13, 1976)

[Government Patent Policy Act of 1980](#) (Dec. 12, 1980)

[Federal Anti-Tampering Act](#) (Oct. 13, 1983)

[Sanitary Food Transportation Act](#) (Nov. 3, 1990)

[Mammography Quality Standards Act \(MQSA\)](#) (Oct. 27, 1992)

[Bioterrorism Act of 2002](#) (June 12, 2002)

[More information about the Bioterrorism Act](#)

[Project BioShield Act of 2004](#) (July 21, 2004)



FDA NEW LAWS

Within the Last 5 years

- The Food and Drug Administration Amendment Act (FDAAA)
 - Signed into law on September 21, 2007 by the President
 - Amends the FD&C Act by creating a new section, 417, Reportable Food Registry
- The Patient Protection and Affordable Care Act (PPAC Act)
 - Signed into law on March 23, 2010 by the President
 - Amends the Public Health Service Act (PHS Act) to create an abbreviated approval pathway for biological products that are demonstrated to be “highly similar” (biosimilar) to or “interchangeable” with an FDA-approved biological product.
- The Family Smoking Prevention and Tobacco Control Act (FSPTCA)
 - June 22, 2009, Signed by the President
 - The law gives FDA the authority to regulate tobacco products and manufacturers.
- The Food Safety Modernization Act (FSMA)
 - January 4, 2011, Signed by the President
 - This laws updated the food laws in areas of recall, frequency of inspections, on import authorities and food manufacturer’s record keeping procedures.



Food Safety Modernization Act

“I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action.”



*Margaret A. Hamburg, M.D.,
Commissioner of Food and Drugs*



Prevention:

The cornerstone of the legislation

- Comprehensive preventive controls for food facilities
 - Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
 - Strengthens accountability for prevention
- Produce safety standards
- Intentional adulteration standards



Inspection, Compliance, and Response

- Mandated inspection frequency
 - Considering new ways to inspect
- New tools
 - Mandatory recall
 - Expanded records access
 - Expanded administrative detention
 - Suspension of registration
 - Enhanced product tracing
 - Third party laboratory testing



Import Safety: Most groundbreaking shift

- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- FDA can rely on third parties to certify that foreign food facilities meet U.S. requirements
- Can require mandatory certification for high-risk foods
- Voluntary qualified importer program--expedited review
- Can deny entry if FDA access for inspection is denied
- Requires food from abroad to be as safe as domestic



For more information



Food Bill Aims to Improve Safety

Recent data from the Centers for Disease Control and Prevention show that one in six people in the United States suffers from food-borne illness each year. Over the past few years, high-profile outbreaks related to various foods, from spinach and peanut products to eggs, have underscored the need to make continuous improvements in food safety.

The Food Safety Modernization Act (FSMA) gives FDA a mandate to pursue a system that is based on science and addresses hazards from farm to table, putting greater emphasis on preventing food-borne illness. The reasoning is simple: The better the system handles producing, processing, transporting, and preparing foods, the safer our food supply will be.

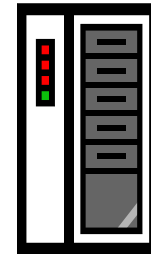
Under the provisions of FSMA, companies will be required to develop and implement written food safety plans, FDA will have the authority to better respond and require recalls when food safety problems occur, and FDA will be able to better ensure that imported foods are as safe for consumers as foods produced in the U.S. FDA Commissioner Margaret A. Hamburg, M.D., says the bill—which President Barack Obama is expected



- www.fda.gov
- www.foodsafety.gov

Newer IT Technologies

- Upgrade IT Technology
 - PREDICT
 - Email Systems – Increased Memory Capacities
 - ITACS
 - Paperless – Electronic Correspondence
- Upgrade Field Tools – Handhelds
- Integration with other FDA Processes





IT TECHNOLOGIES AT FDA

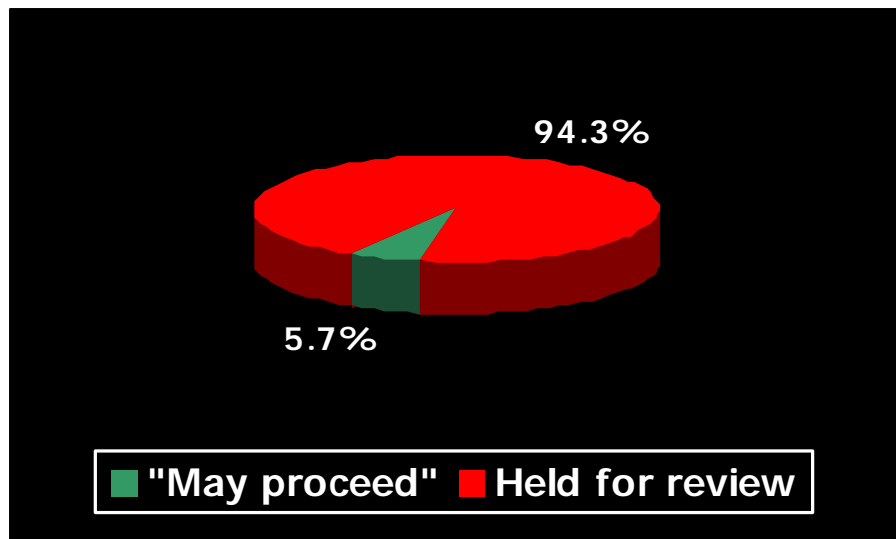
Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

- New risk assessment tool
- Assesses relative risk of food, comparability of country, intelligence, data mining
- Increases speed of FDA releases for low risk foods/comparable countries; reduce sampling and exams
- Focus on high risk foods/minimally or non-comparable countries- increase sampling and exams
- MARCS Entry Review and PREDICT were deployed to Los Angeles District in late September 2009, to New York District in March 2010, and to San Francisco and Seattle districts in October 2010.
- At Los Angeles, the May Proceed rate on entries is about 45%. Highest rate compared to other districts. – Providing accurate data to FDA at the beginning of data submissions to ABI.

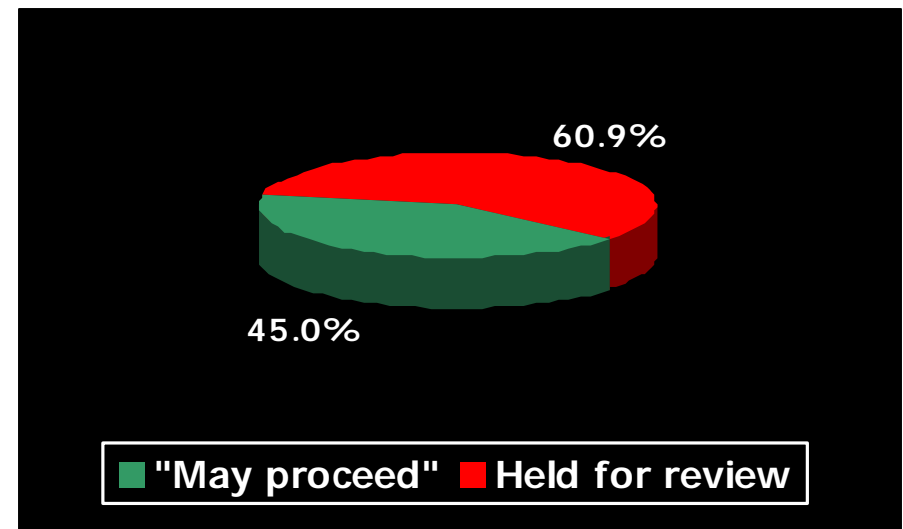


Effective rates – Automated “may proceed”

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.



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 “hit” rate for exams and samples by –
 - Scoring **each entry line on the basis of risk factors** and surveillance requirements
 - Increase the number of **automated, real-time**, risk-based “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

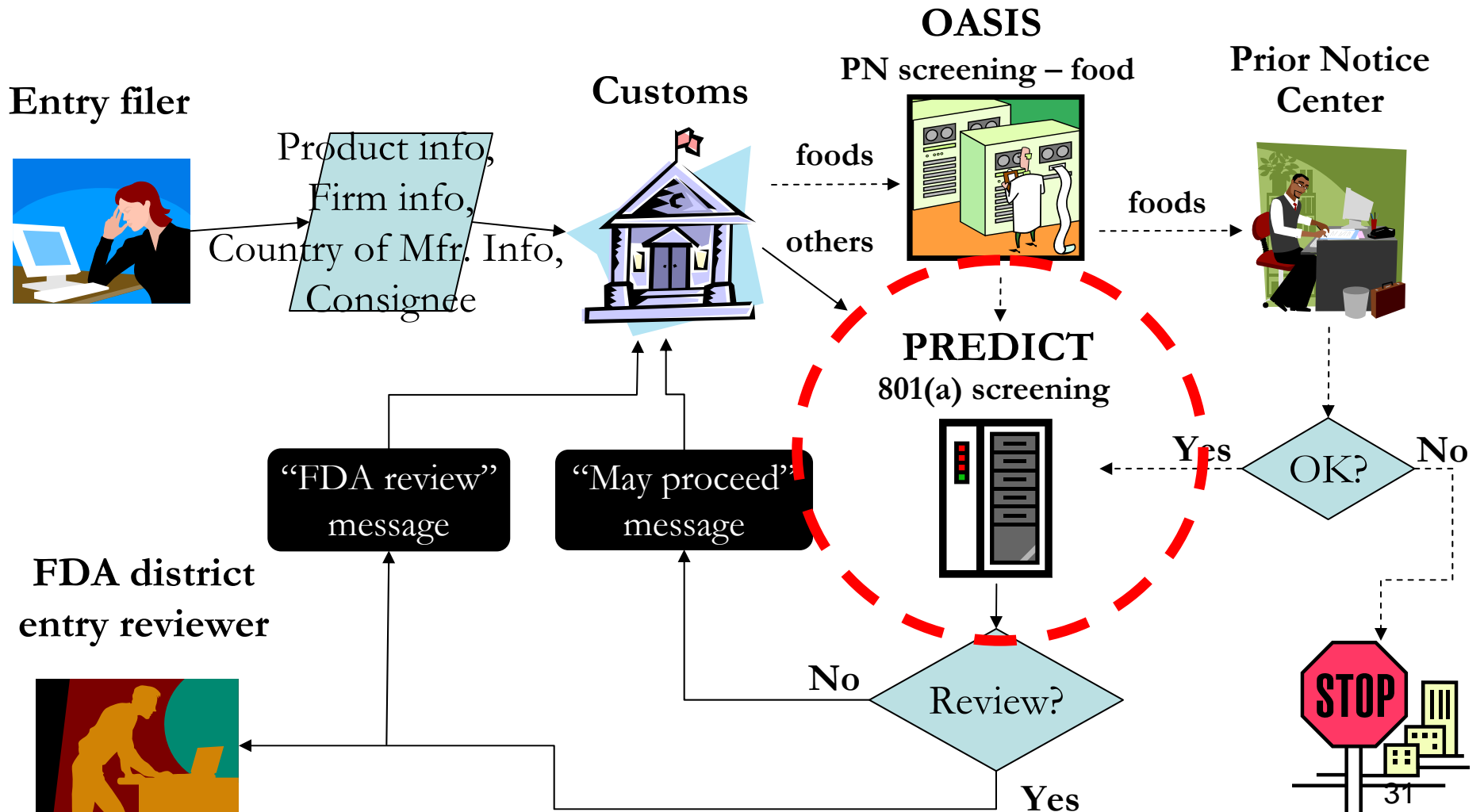


Examples of source data for PREDICT screening rules

- 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.



IMPORT PROCESS





FDA district
entry reviewer

Field exam



Documents
requested
by FDA

Initial action?

“May proceed”
message

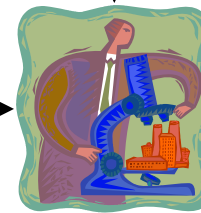
Detain w/o
physical exam

???

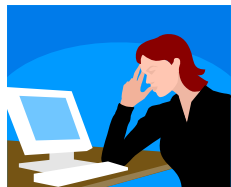
Results?

Good

Bad



Sample,
analyze



Entry filer

Detain

Release with
comment

Release

IB release

Compliance
action



Compliance
Officer



ITACS

Import Trade Auxiliary Communications System

- Internet portal for entry filers to
 - Check the status of individual entries/lines
 - Submit documents and link them to specific entries/lines
 - Provide availability information for targeted shipments
- Submitted documents will be readily available to entry reviewers



How To Speed Through the FDA Process

Submit Good, accurate product Information when submitting to CBP via ABI

For REFUSED entries:
Schedule with the REFUSAL Department when you want to Destroy or Export the goods or merchandise

Provide Information to FDA Investigators when Requested

Have Goods Ready for FDA Investigators and provide locations as early as possible.

Find out who is in charge of your case and communicate with that Officer only. Sending an email or calling multiple phone numbers will only delay your entry

DO NOT
Distribute Goods until you get an FDA Release



FORMS OF COMMUNICATION WITH FDA in LOS ANGELES IMPORTS

- **Phone Calls**
- **General email address: LAIMPORTS@fda.hhs.gov**
- **And LAXImports@fda.hhs.gov**
- **Adobe pdf documents can be accepted.**
- **General status line (310) 971-2280**
- **Or Compliance status line (310) 971-2399**
- **Fax line (310) 971- 2360**
- **Appointment**
- **Outreach Events**

Note: Using multiple communication forms will only slow down your response to your question. USE ONE OF THE ABOVE. Fastest response is email.



Leadership

Health and Human Services Secretary Kathleen Sebelius





Leadership

FDA Commissioner Margaret Hamburg

“We will hold ourselves to the highest standards of transparency and accountability and give our partners and stakeholders insight into our processes and decision making. “

9/29/10





Thank You For Your Attention

Dan R. Solis

FDA Director of Import Operations

Los Angeles District

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QUESTIONS?