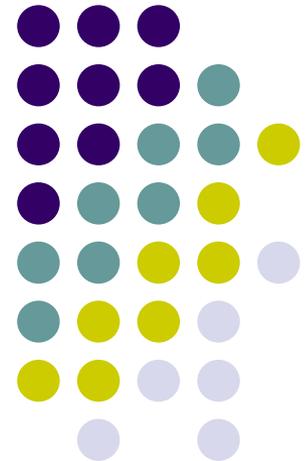


Division of Foreign Field Investigations

Susan Laska
Deputy Director Division
Foreign Field Investigations





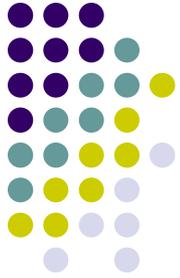
The DFFI Mission



- Support & participate in foreign field inspectional & investigational operations
- Coordinate investigational activities international arenas
- Focal point of foreign investigational issues between headquarters units and field offices
- Develop/evaluate agency policy & procedures for investigations/inspections
- Assist in the development of training
- Evaluate new equipment and technology for use during foreign inspections



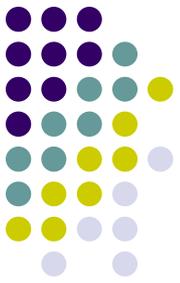
Responsibilities



- Set-up of foreign inspections
 - Monitor traveler safety
 - District office for international inspection activities
 - Issue assignments to Global Offices
 - Review work products from the Global Offices
 - Plan non-regulatory travel

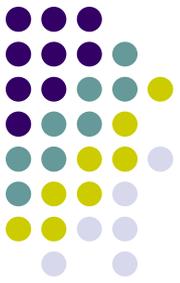


FDA's International Inspection Program



- We have been conducting international inspections since 1955.
- Overseeing
 - The International Inspections
 - The scheduling of all program area inspections
 - Planning non-regulatory travel for capacity building and speeches, etc.

PROGRAM OBJECTIVES



- Coordinate foreign travel for ORA
- To accomplish over 2,800 FDA International Inspections in FY-11
- To ensure the most efficient use of budget and human resources.





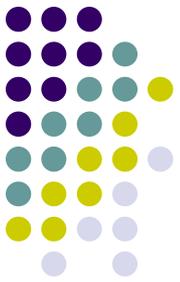
Assignments



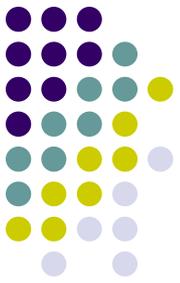
- Firms to be inspected are received from the CFSAN, CDER, CDRH, CVM, CBER also ORA
- Organizes firms into trips based on traveler availability, priority, and location.
- Trips are created for 3 or 4 weeks
 - Medical products average of 3 inspections
 - Foods 5-8 inspections



Trip documents...



- Trip itinerary
- Final Travel Package
 - Prepared by the Trip Coordinator and may include:
 - Maps, inspection itinerary, embassy form(s), travel warnings, Consular Information Sheets (issued by the State Dept.), official passport, travel authorization, overtime authorization, cellular phone, informational coversheet, calling card guide, etc.



Challenges in Trip Coordination

- Short deadlines – outbreak follow-up
- Multiple priorities within different Centers
- Information provided by different sources
- Availability of travelers
 - Domestic vs. international work plan
- Availability of firms
 - Time difference
 - Communication
- Natural disasters (i.e. Japan, floods in SA, State department restrictions)



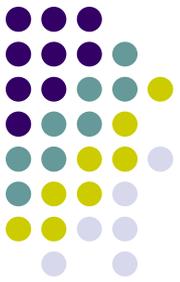
Foreign Inspection Drivers



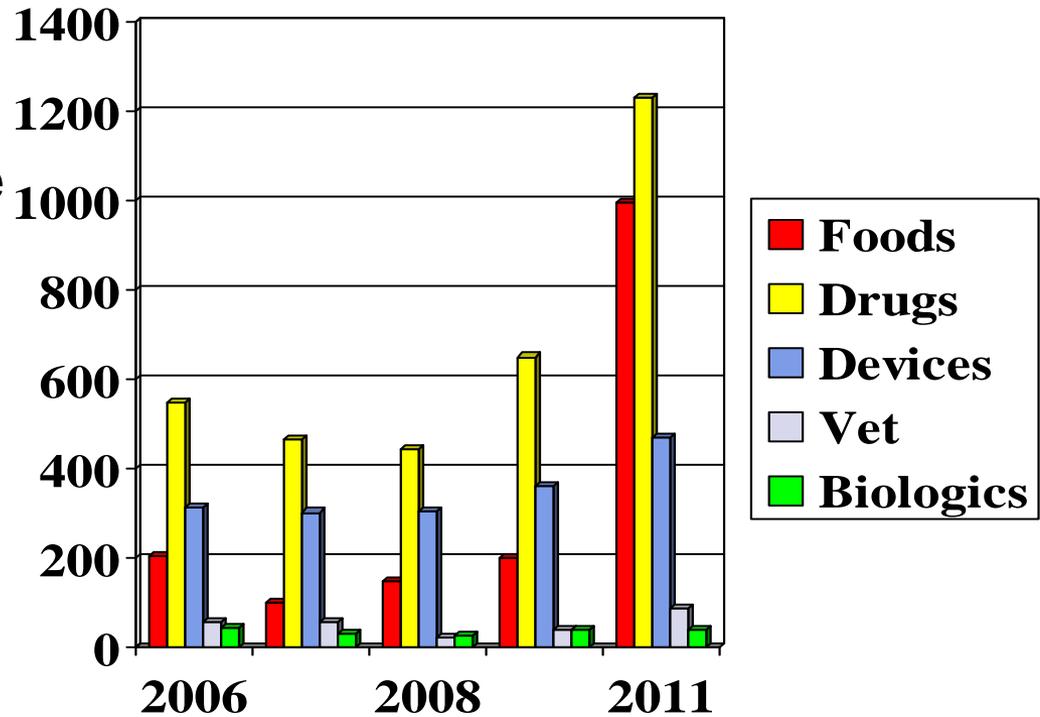
- Statistics: Imports vs. Inspections
 - Imports, foreign manufactures, # of inspections
- Inspections are part of the answer
 - The question: How do we increase our compliance base understanding of foreign firms?
 - Foreign Registration
 - Information from foreign governments (ex. Recalls)
- Work plan & Product approval process
- MRAs & International Agreements



International Inspection Numbers



- Factors which result in inspections
 - Pre-Approval Submissions (PEPFAR)
 - Routine surveillance
 - Post approvals
 - F/U
 - Food assessments
 - MOUs/international agreements
 - Import issues
 - Emergencies



International Inspection Program

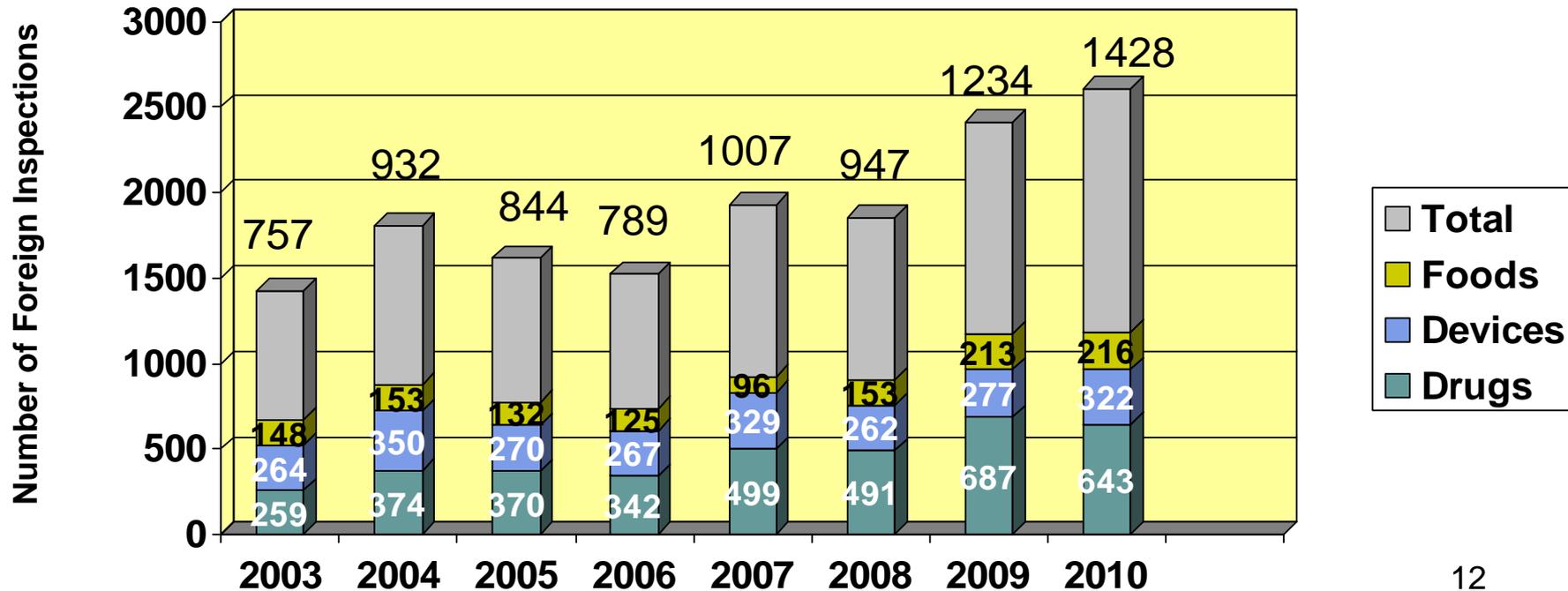


- Historically
 - Approximately 1300 CSOs
 - International Inspection Cadre
 - Over 500 CSOs/Analysts in the Cadre
 - Nomination process and type of people in the cadre
- Current state we have @ 4000 CSO's in Field
 - Approximately 400 CSO capable of foreign inspections
 - Approximately 150 analysts capable of foreign inspections
- Inspection Trip
 - 3 weeks in length
 - 1-2 inspections per week
 - Travel between cities on weekday or weekend

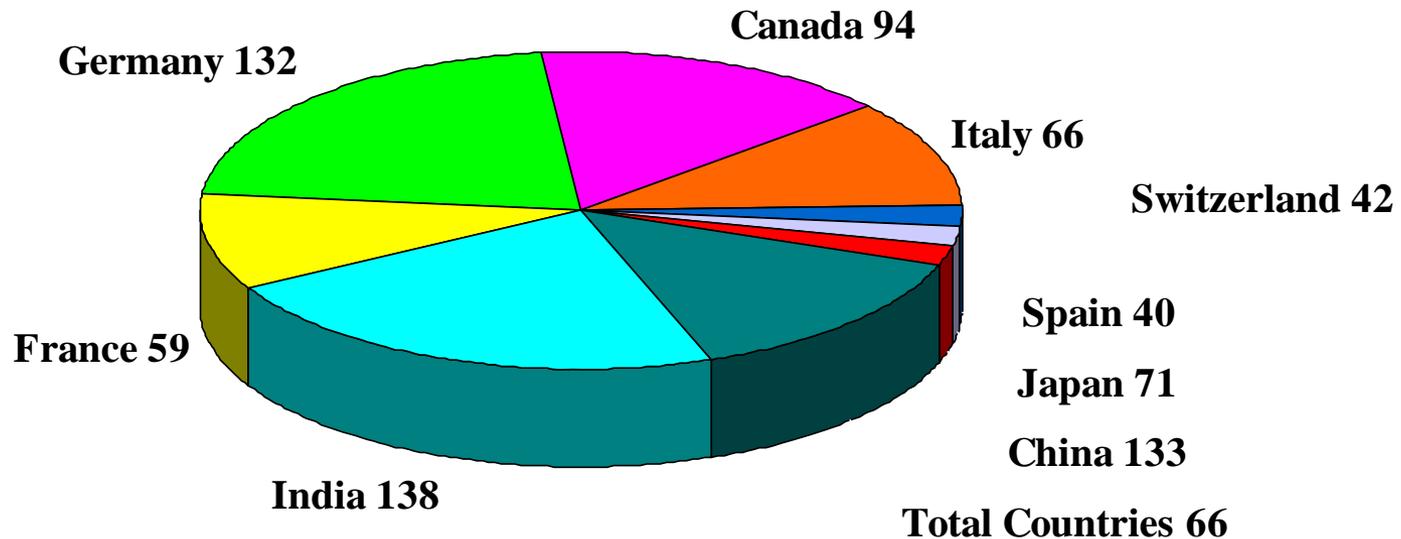
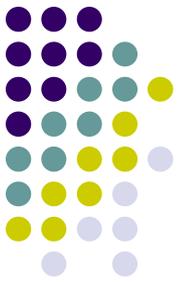


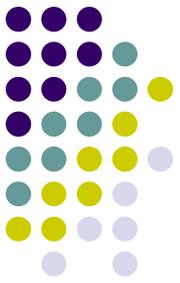
FDA's Foreign Inspection Accomplishments

- FDA accomplished more foreign inspections in FY10 than at any other time in our history.



FDA's International Inspections By Country, FY 2010





Globalization

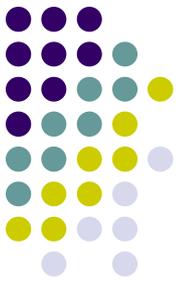
* China – Beijing, Shanghai and Guangzhou offices

* India – Mumbai & New Delhi

Latin America – Costa Rica, San Jose & Mexico City

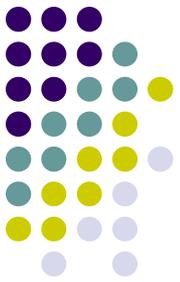
Europe – Brussels & London

Global Offices



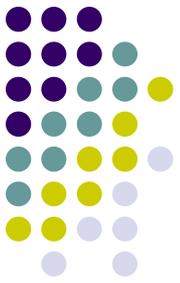
- Agreements with foreign governments (Example: China)
- Improve cooperation and info exchange
- More easily facilitate inspections or changes to inspections/schedules
- Quicker inspections during emergency
- Work with private and government agencies to ensure quality standards

Dedicated Cadre



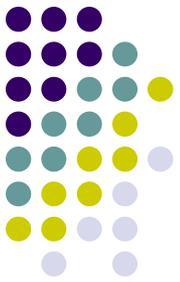
- First trips started in 2/09
- Currently
 - Drug, Device and Food
- 1 Year term – options to renew

Food Safety Modernization Act



- First time ever an inspection mandate including foreign inspections
- Inspection approach to preventative controls framework to enhance public health focus – more inspections

Status



- Global OEI
- More international work - FSMA
- Congressional Mandates