



Globalization and the FDA

The Alliance for a Stronger FDA

Quarterly Member Meeting

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FDA's Responsibilities

FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation, and by regulating the manufacture, marketing and distribution of tobacco products



Presentation Overview

- I. Organizational Changes in the Office of the Commissioner (July 2011)
- II. Globalization Challenges and Realities FDA Faces
- III. What FDA is Doing to Address These Challenges
- IV. New Legislative Authorities
- V. Path Forward



I. Organizational Changes in the Office of the Commissioner (July 2011)



Organizational Changes

- Office of the Commissioner
 - Counselor to the Commissioner
 - Office of the Chief Scientist
 - Office of the Executive Secretariat
- Directorates
 - Office of Operations
 - Office of Foods
 - Office of Medical Products and Tobacco
 - **Office of Global Regulatory Operations and Policy**



Office of Global Regulatory Operations and Policy

- Office of Global Regulatory Operations and Policy (GO)
 - Office of Regulatory Affairs
 - Office of International Programs
- Ensures that FDA integrates its domestic and international programs



II. Globalization Challenges and Realities FDA Faces



Globalization

- Foreign production of FDA-regulated goods and materials has exploded over the last decade
- FDA-regulated products originate from more than 150 countries:
 - 130,000 importers
 - 300,000 foreign facilities
- 24 Million shipments arrive at >300 U.S. ports of entry annually
- Distinction between domestic and imported products is obsolete
- Global supply chain is more complex
- Growth is expected to continue

A high end estimate anticipates a tripling of imports of FDA-regulated products between 2007-2015, corresponding to a 15% growth rate



Globalization - Production

- Food
 - 10-15% of all food consumed by U.S. households is imported
 - Nearly 2/3 of the fruits and vegetables
 - 80% of seafood eaten domestically come from outside the U.S.
 - Food imports have increased an average of 10% per year from 2005-2011

- Devices
 - Medical device imports have grown at over 10% per year from 2005-2011
 - Half of all medical devices used in the U.S. are imported

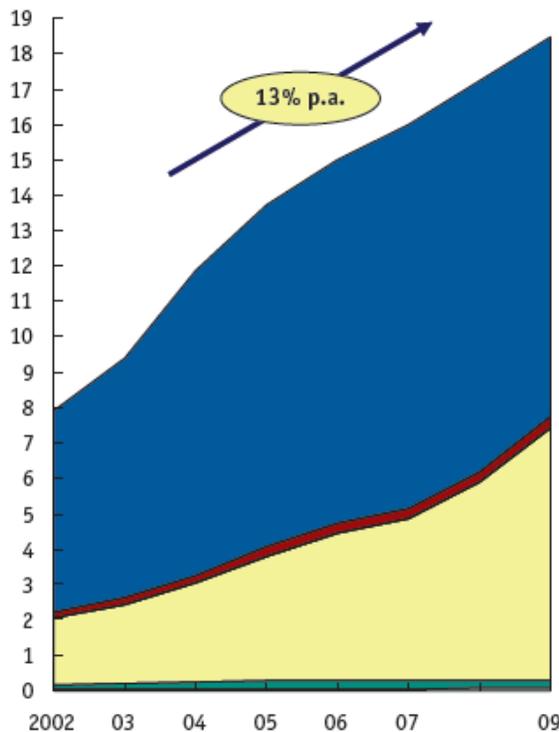
- Drugs
 - 80% of API used in the U.S. are manufactured abroad
 - 40% of finished drugs are manufactured abroad
 - Pharmaceutical product imports increased at nearly 13%/year from 2005-2011



Import shipments of FDA-regulated products have been growing at 13 percent per year.

Imported lines¹(millions)

Total = 7.9 MM in 2002; total = 18.5 MM in 2009



CAGR

2002-09 Explanation of center's products

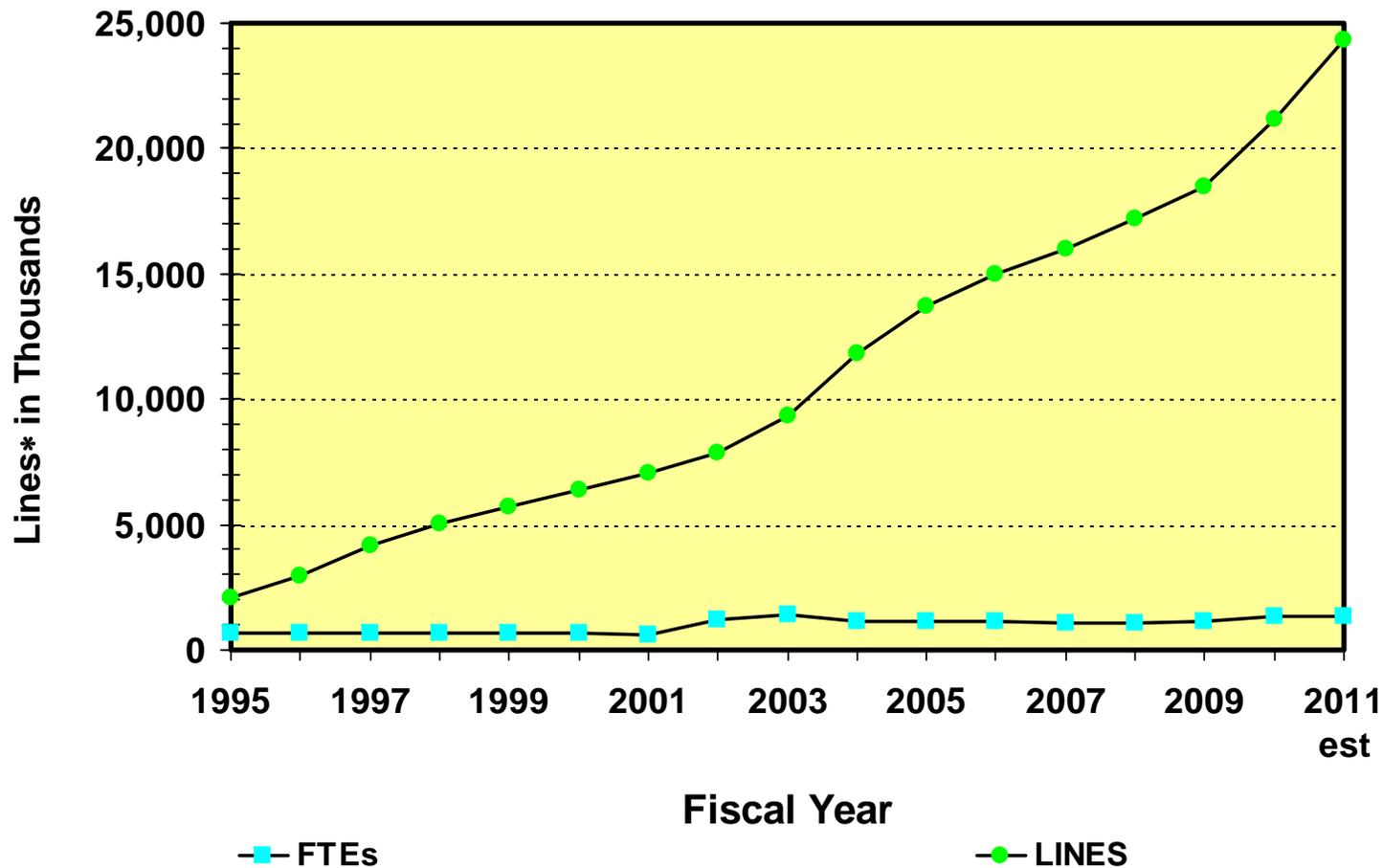
Category	CAGR	Explanation of center's products
Foods	9.5%	<ul style="list-style-type: none"> Food products for human, animal, pet use, except meat and poultry Articles for cleansing, beautifying, promoting attractiveness of body
Drugs	12.9%	<ul style="list-style-type: none"> Prescription and OTC drugs for human
Devices	20.8%	<ul style="list-style-type: none"> Medical devices for human use Products that emit radiation (e.g., microwaves, lasers, x-ray machines)
Veterinary products	6.7%	<ul style="list-style-type: none"> Drugs, devices, and food additives for animals and pets
Biologics	15.8%	<ul style="list-style-type: none"> Blood products, vaccines, and tissues for transplantation

¹ An import line represents the portion of a shipment listed as a separate item on an entry document. The number of units can vary.

Source: FDA



FDA Resources Fail to Keep Pace



*Lines are shipments of a certain type of product (i.e. if a container includes 1 million bottles of water and 5 million bottles of club soda, that would be one entry containing two lines).



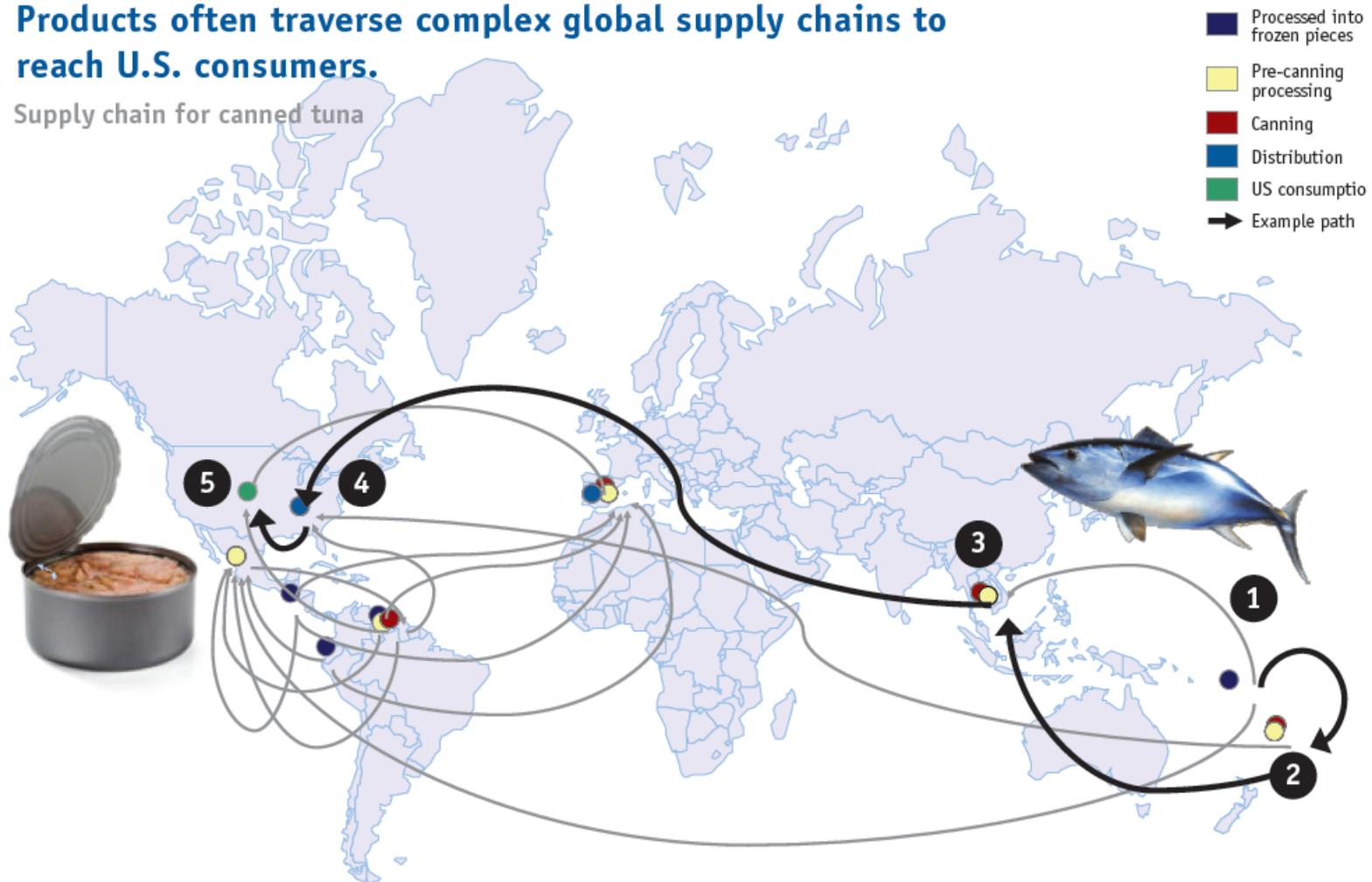
Global Supply Chains

- Between 2000 and 2007, the U.S. quadrupled its importation of “high risk” medical products, such as vaccines.
- 70 to 85% of food import refusals of produce and seafood were for potentially dangerous violations including the presence of pathogens, chemical contamination, and “other sanitary violations.”
- Complex medical devices - once primarily manufactured in U.S. – are increasingly manufactured overseas.

Changing Nature of Risk in Global Supply Chains

Products often traverse complex global supply chains to reach U.S. consumers.

Supply chain for canned tuna





Global Supply Chains

- Increased number of individuals, producers, and companies geographically dispersed
- Growing availability of distribution channels for products (e.g., Internet)
- Intentional adulteration and counterfeiting for economic or other reasons
- Product mobility



III. What FDA Is Doing to Address These Challenges

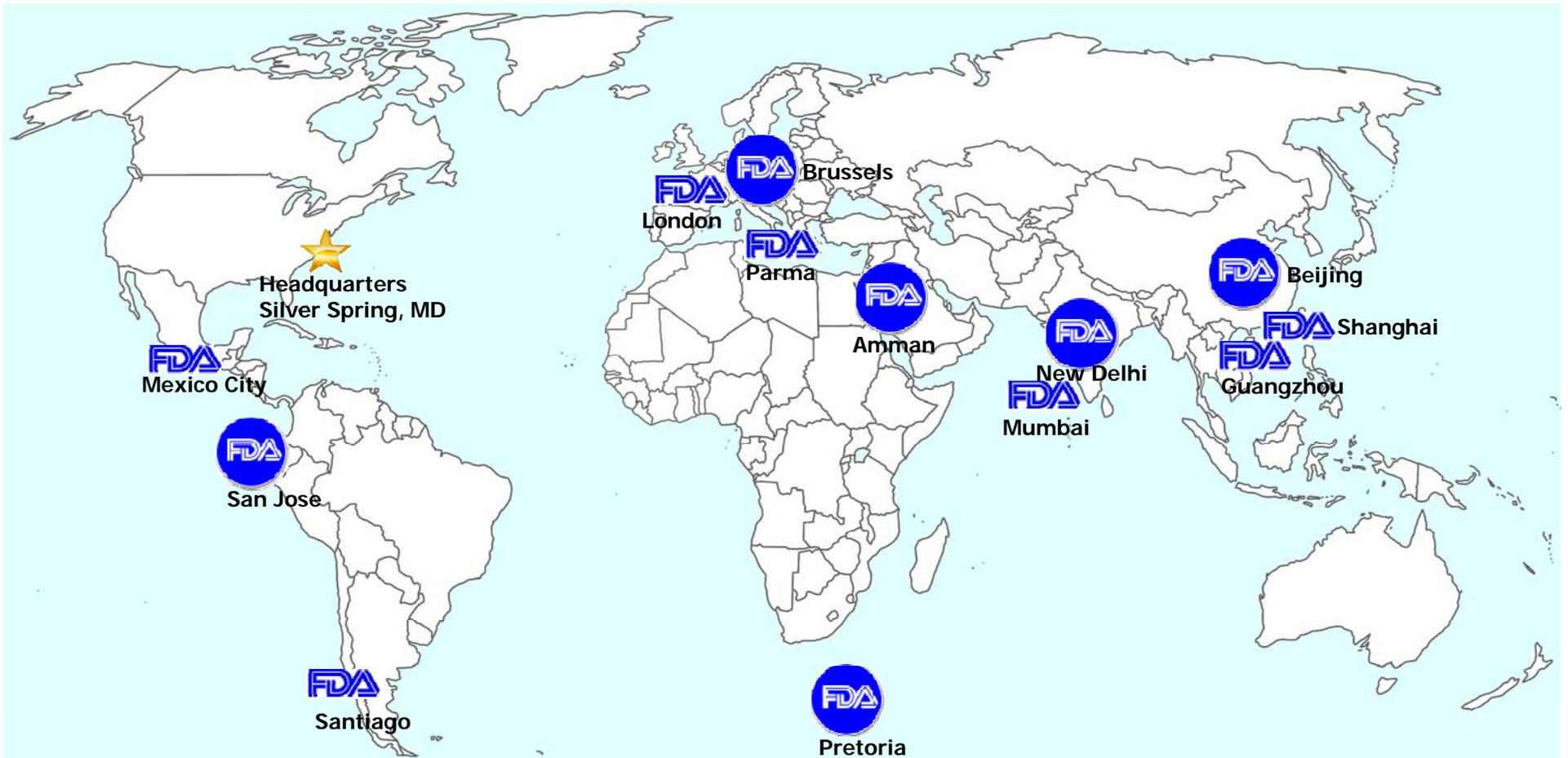


FDA's Efforts

- Establishment of foreign offices
- Increased foreign inspections
- Dedicated cadre of foreign inspectors
- PREDICT

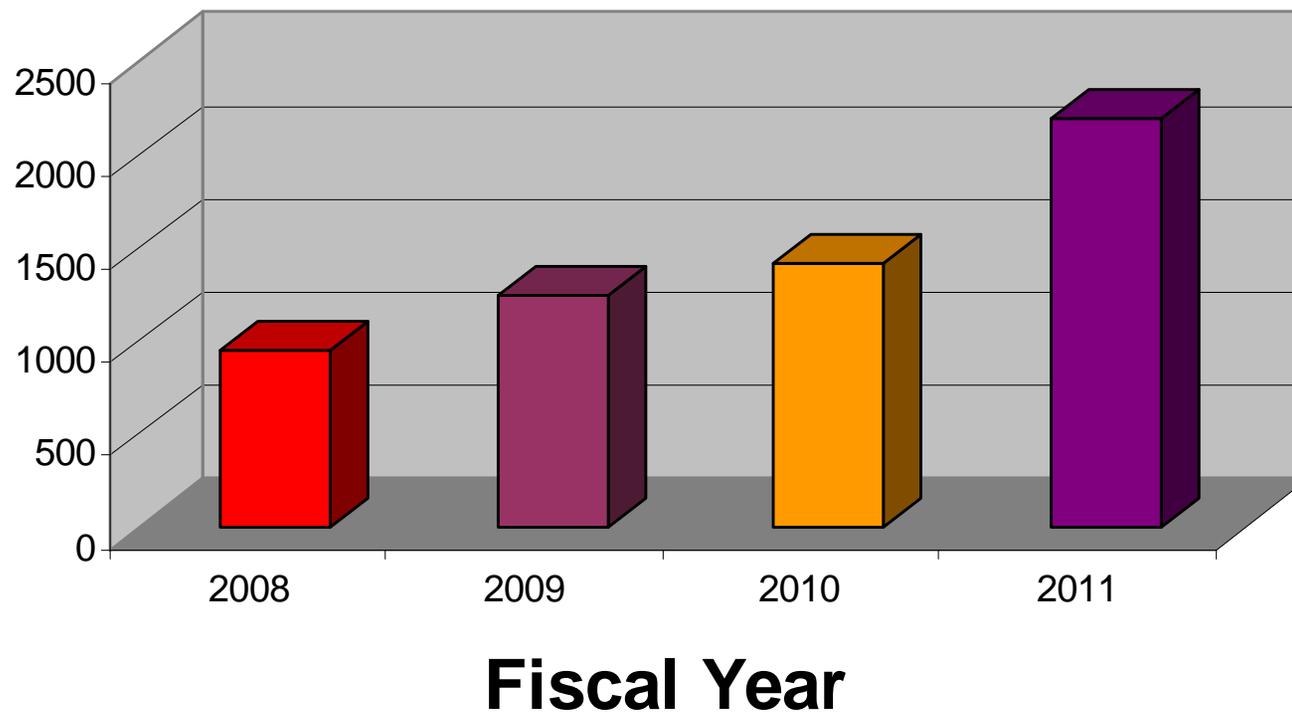


FDA Foreign Offices





Foreign Inspections





FDA's Global Work

- Collaboration with EMA, TGA
- PIC/S Membership
- International Medical Device Regulators' Forum
- Single Audit Initiative
- International Tobacco Regulators' Conference
- Multi-Donor Trust Fund for food safety capacity building
- CODEX
- Many More...



How Industry Can Help

- Invest in quality
- Implement and follow cGMPs and GCPs
- Embrace corporate accountability
- Ensure quality systems are in place
- Deploy resources effectively
- Work with regulatory partners
- Institute preventive controls
- Investigate and act on non-conformities
- Notify and communicate with FDA when public health issues arise



IV. Need for New Legislative Authorities



Legislative Drug Authorities

- FDA Modernization and transformation are necessary to ensure patient safety and appropriate legal authorities are critical to this goal

- Paradigm Shift
 - Level the Playing Field
 - Improve Product Safety
 - Increase Information Sharing

- Resources



Advantages for Industry

- Advantages for industry may include:
 - Fewer inspections
 - Stream-lined regulation
 - Level playing field between foreign and domestic producers
 - Elimination of the competitive advantage of non-compliance



V. Path Forward



Global Pathway Report

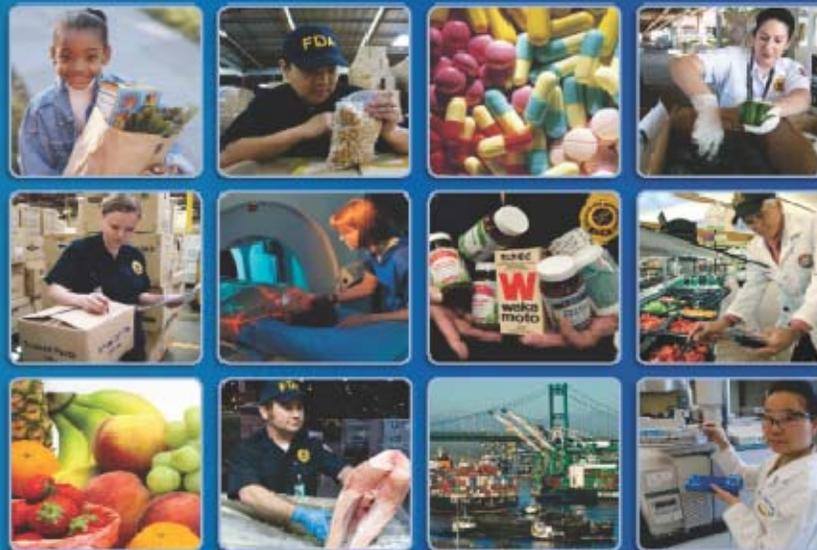
- FDA formed a Globalization Steering Committee, a cross-section of agency experts tasked with:
 - Developing a framework and action plan to guide the future regulation of FDA imported products, and
 - Addressing globalization challenges of 10 years down the road, as well as those of today.
 - The future is a public health safety net for consumers around the world created by global coalition(s) of regulators.



U.S. Food and Drug Administration
A Special Report



Pathway to Global Product Safety and Quality



<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/GlobalProductPathway/UCM262528.pdf>



Four Pillars

- Partner with foreign counterparts to create global coalitions of regulators focused on ensuring and improving global product safety
- Build global data information systems and networks and proactively share data with peers
- Expand intelligence gathering, with an increased focus on risk analytics and thoroughly modernized IT capabilities
- Effectively allocate agency resources based on risk, leveraging the combined efforts of government, industry and public and private third parties



Global Coalitions of Regulators

- Maintain and respect sovereignty
- Rely on common, science-based standards
- Focus on comparability, not equivalence
- Learn from other operating and governance models



Global Data Information Systems

- Identify critical data elements
- Standardize reporting
- Create a process for regular, systematic information exchange
- Implement data sharing mechanisms



Intelligence Gathering Focused on Risk Analytics

- Identify signals and warnings about potential risks before they occur
- Determine how to monitor those signals
- Enhance risk analytics capabilities
- Build a supporting infrastructure that enables experts to readily access and analyze data



Leverage Third Parties

- Uses intelligence to align and deploy resources more effectively against risk-based priorities
- Allows FDA to maintain broad-based oversight but enlists others to conduct audits and activities on behalf of FDA
- Creates flexibility to shift resources to most pressing dangers
- Treats like risks in equivalent ways, regardless of geographic location



Conclusion

- Over the next decade, FDA will continue to transform from a predominantly domestically focused Agency, operating in a globalized economy, to an Agency fully prepared for a regulatory environment in which FDA-regulated products know no borders.
- This monumental effort will take a long-term investment in time and resources, however the pay off will be added safety and security for American consumers.



Questions?