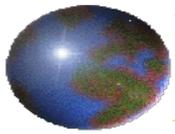


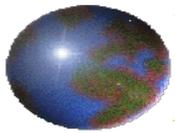
U.S. Food and Drug Administration Office of International Programs and International Offices

*Presenter: Nicole Taylor Smith, Assistant Country Director
China Office, U.S. Food and Drug Administration*



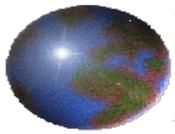
Overview

- ✦ FDA's Mission & Background
- ✦ New Challenges and Risks in a Globalized Marketplace
- ✦ FDA's Strategies and Engagement to Address Challenges and Risk



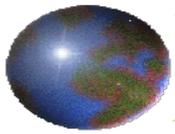
FDA - Mission

- ✚ Protect the public health – assuring safety, efficacy, and security of products it regulates
- ✚ Promote public health
- ✚ Collaborate with scientific experts, academia, industry and consumers
- ✚ Foster Innovation
- ✚ FDA Globalization



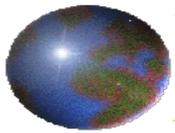
FDA - Key Facts

- ✦ The oldest consumer protection agency in the U.S. federal government (formed in 1906)
- ✦ Broad responsibilities
- ✦ Regulatory and law enforcement authorities
- ✦ Regulates >\$1 trillion worth of consumer goods
 - ▣ nearly 25 cents of every dollar spent by Americans
 - ▣ accounts for about 10% of all imports into the U.S.



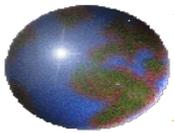
FDA - Past

- ✦ FDA traditionally a domestically-focused agency
- ✦ Congress kept regulatory lens narrow
- ✦ Industry oversight concentrated on those companies within U.S. boundaries
- ✦ Previously worked because the volume of imports was low and the movement of goods across the country and world was minimal



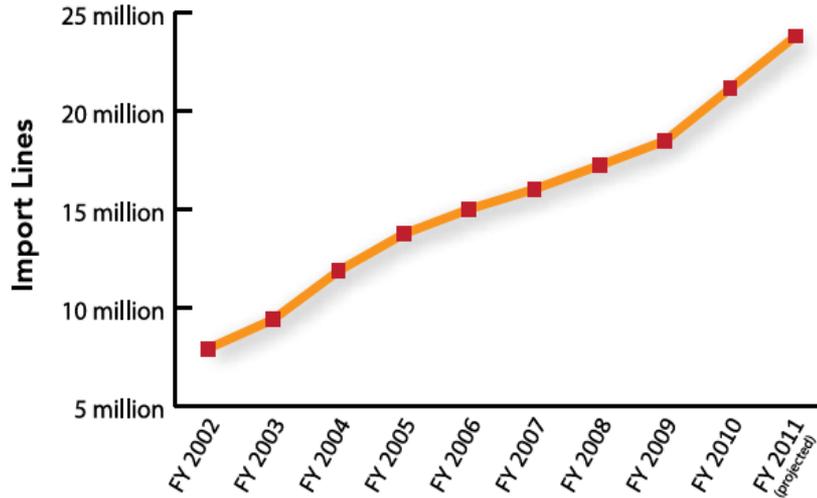
FDA - Present

- Foreign production of FDA-regulated goods and materials has exploded over the last decade. Number of FDA-regulated shipments has quadrupled over ten years
 - Now more than 24 million shipments annually
 - Estimates anticipate that the number of imports of FDA-regulated products will triple between 2007 and 2015
- FDA-regulated products originate from more than:
 - 150 countries; 130,000 importers; 300,000 foreign facilities; over 300 U.S. ports
- Approximately half of medical devices are imported



Imports of FDA-Regulated Products

Imports of FDA-Regulated Products Have Grown Dramatically in Recent Years

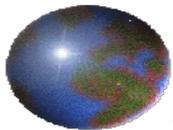


FY = U.S. Government fiscal year

NOTE: An import line represents the portion of a shipment listed as a separate item on an import entry document. Items must be listed separately if their tariff description differs from other items in the shipment.

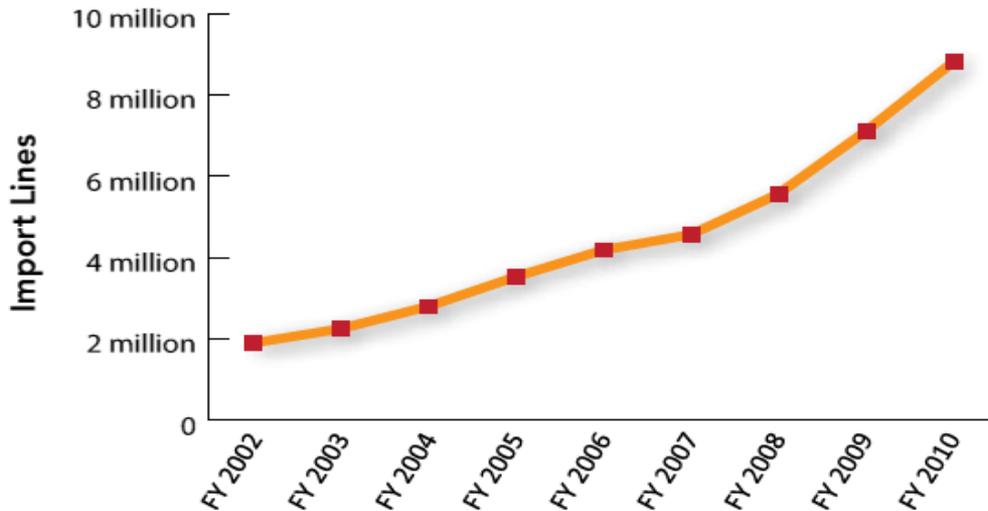
Source: Veneziano, D. 2011. *Import Stats FY 2002-2010*. U.S. FDA, Division of Import Operations and Policy, Office of Regulatory Affairs, Washington, DC.

From Global Engagement report, available:
<http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/ucm2016758.htm>



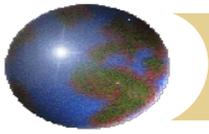
Imports of Medical Devices

Medical Device Imports Have Increased Over 450 Percent Since 2002

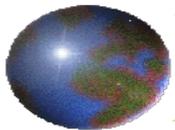


Source: Veneziano, D. 2011. *Import Stats FY 2002-2010*. U.S. FDA, Division of Import Operations and Policy, Office of Regulatory Affairs, Washington, DC.

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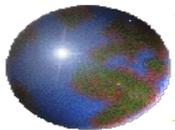


New Challenges and Risks in a Globalized Marketplace



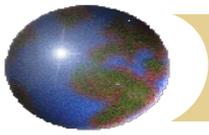
Global Marketplace - New Challenges

- ✦ Increased production of FDA-regulated products and global production of products, increased number of imports, increased need for stronger regulatory systems
- ✦ Risks associated with greater numbers of suppliers, more complex products, broader distribution channels (e.g., Internet), and intricate multinational supply chains
- ✦ Increasing pressure to reduce costs and increase productivity in a global marketplace

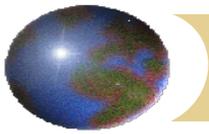


Global Marketplace - New Challenges

- ✦ Inspections at the U.S. borders or ports-of-entry is no longer sufficient to ensure the safety of products
- ✦ Intentional adulteration and counterfeiting for economic or other reasons
- ✦ Increasing number of clinical trials of new medical products conducted abroad

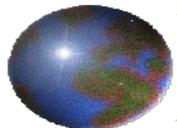


FDA's Strategies and Engagement to Address Challenges and Risk



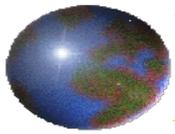
“Today we recognize that to successfully protect U.S. public health, we must think, act, and engage globally. Our interests must be broader than simply those within our borders.”

- Margaret Hamburg, FDA Commissioner



Need for Change and Transformation

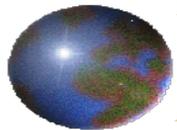
- ✚ FDA is committed to substantially and fundamentally revising its approach to global product safety and quality
- ✚ Developing an international operating model that relies on enhanced intelligence, information sharing, data-driven risk analytics, and smart allocation of resources through partnerships



Need for Change and Transformation

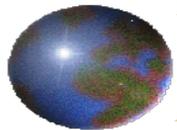
- ✦ Over the next ten years FDA will transform itself from a domestic agency operating in a globalized economy to a truly global agency fully prepared for the regulatory pressures of globalization

- ✦ To achieve this transformation, FDA is developing an international operating model with four core building blocks:
 1. Global coalitions of regulators
 2. A global data information system and network
 3. Expanded capabilities in intelligence gathering and use
 4. Allocation of Agency resources based on risk



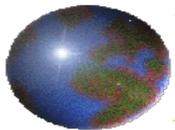
Efforts to Address Challenges

- ✦ Organizational changes
- ✦ Establishment of foreign offices
- ✦ Increased foreign inspections
- ✦ Dedicated cadre of foreign inspectors
- ✦ PREDICT system - using risk-based data and analytics from the entire lifecycle of the product and open source intelligence

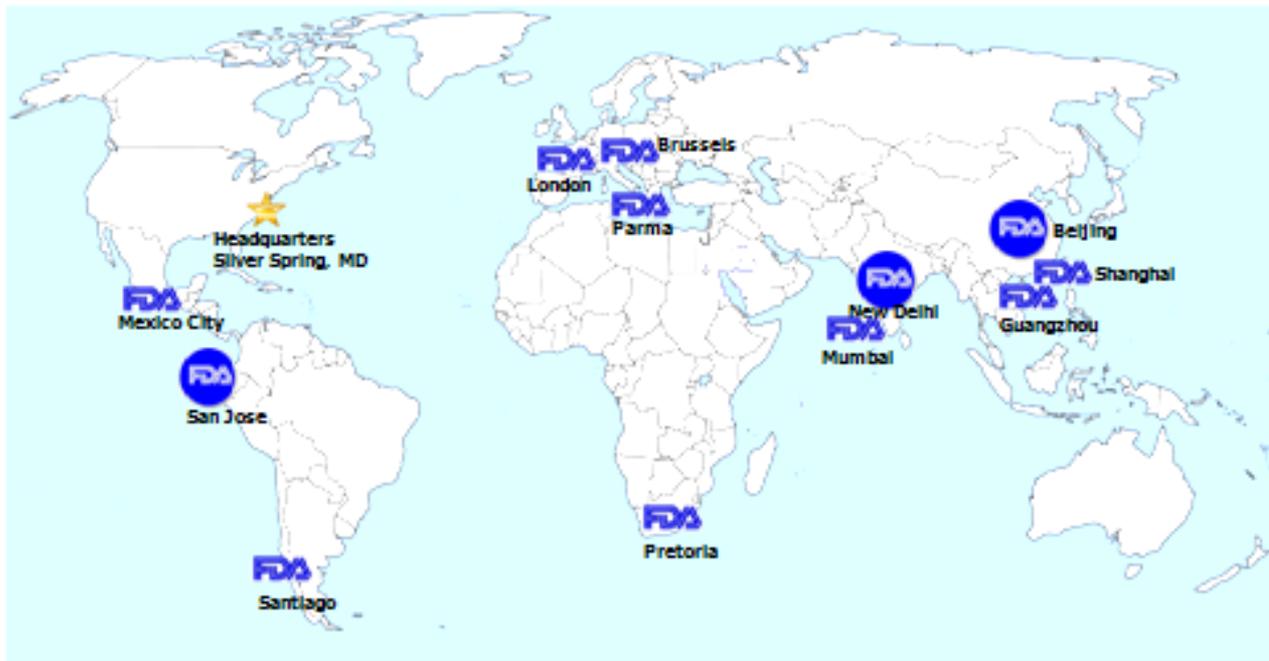


Efforts to Address Challenges

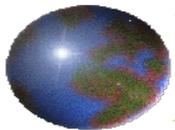
- ✚ Global collaborations to harmonize standards and leverage resources
- ✚ Investing to strengthen regulatory systems abroad
- ✚ Efforts to combat counterfeit and substandard products
- ✚ Implementation of legislative mandates



FDA's International Offices

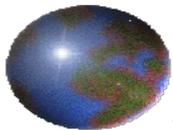


- In 2008, FDA received special U.S. Congressional appropriations to establish offices overseas
- First Office opened in 2008 in China
- Today, 12 posts in 10 countries on 4 continents

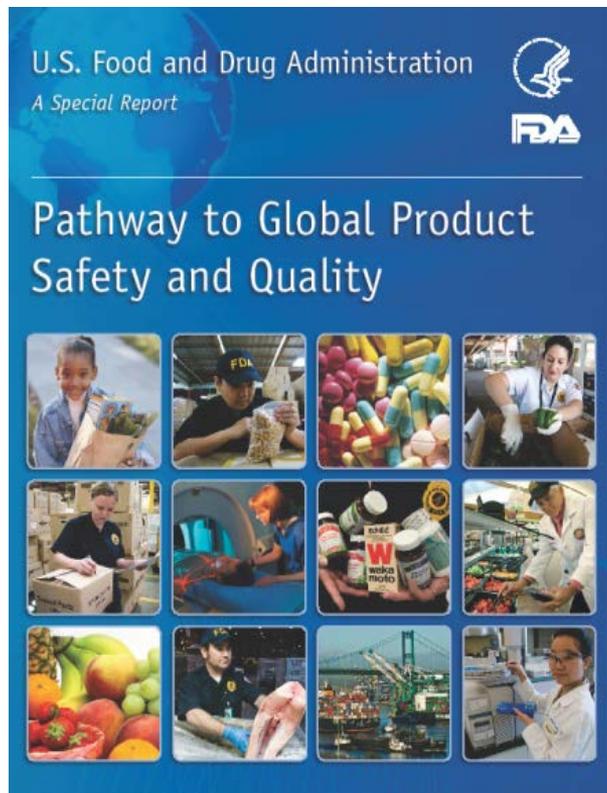


FDA's International Offices





Pathway to Global Product Safety & Quality

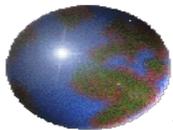


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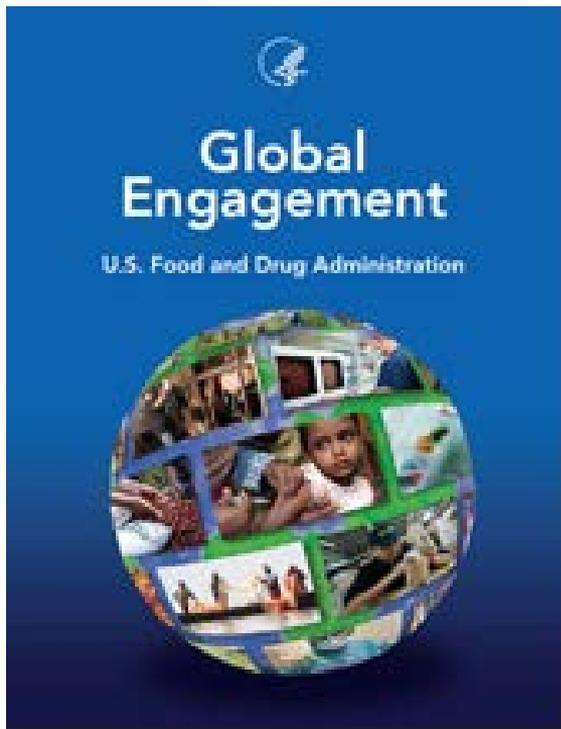
Pillars of Global Pathway

- ✦ **Partner with foreign counterparts** to create global coalitions of regulators to ensure and improve 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 combined efforts of government, industry and public and private third parties

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



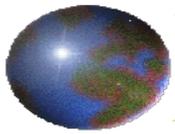
Global Engagement Report



April 2012

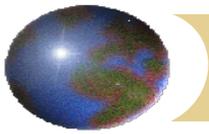
FDA's success in protecting the U.S. public depends increasingly on its **ability to reach beyond U.S. borders** and engage with its government regulatory counterparts in other nations, as well as industry and regional and international organizations, to help **ensure the quality and safety of products** before they reach the United States.

Through **effective global engagement**, FDA is working with its many international partners to weave a **global safety net** that benefits public health in the United States and around the world.



Summary

- ✦ Meeting the challenges of globalization requires fundamental shift in the way that FDA operates
- ✦ Transform from a domestic safety agency operating in a globalized world to an agency that is fully prepared for a rapidly changing global environment
 - ✦ Border can no longer be the primary line of defense
 - ✦ Need preventive controls throughout the supply chain
 - ✦ Need to partner with others to achieve greater levels of safety and security with fewer, more targeted resources



“As our world transforms and becomes increasingly globalized, we must come together in new, unprecedented, even unexpected, ways to build a public health safety net for consumers around the world.”

- Margaret Hamburg, FDA Commissioner