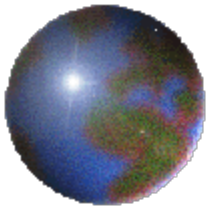

US FDA International Update

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FDA's Statutory Mission

- **(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements;**

INTERNATIONAL WORK

- **DISCRETIONARY ?**
- **INTEGRAL ?**

Basic Principal: International Cooperative Activities

- **Bilateral and multilateral efforts:**
  - **to *leverage* the human, scientific, and financial resources and the knowledge and experience of other key regulatory authorities**
    - **to avoid duplication of effort,**
    - **to make our activities more efficient**
    - **to allow us to focus our limited resources on higher-risk areas of concern.**

Venues and Tools

Venue:

- **Bilaterally**
- **Regionally or multilaterally**
- **Multilaterally with major International Organizations**
  - **WHO, PAHO, FAO, OIE, OECD, APEC**

Tools:

- **FDA's Agreements Umbrella**
  - **Confidentiality Commitments**
  - **Memoranda of Understanding/Agreement or Exchange of Letters**
  - **Implementation or Action Plans**
  - **Formal Harmonization activities**

FDA's Collaborations (Agreements)

- Over 100 bilateral agreements
- Confidentiality Commitments
  - 17 Countries
  - European Commission (2 different DGs)
  - World Health Organization
  - EDQM
- Most tools for information exchange; others developed affirmative collaborations.

Confidentiality Arrangements

- Don’t require us to do anything
- They are a TOOL if we chose to use it
- Allows exchange of otherwise non-public information EXCEPT trade secret and personal
  - Commercial confidential, investigative, pre-decisional

Confidentiality Commitments

- Australia
- Belgium
- Canada
- Denmark
- EDQM
- EU
- France
- Germany
- Ireland
- Israel
- Japan
- Mexico
- Netherlands
- New Zealand
- New Zealand-Australia
- Singapore
- Sweden
- Switzerland
- South Africa
- United Kingdom
- World Health Organization

Wake Up Calls of 2007-08

- Melamine in pet food - China
- Melamine in infant formula and dairy products - China
- Over-sulfated chondroitin sulfate in heparin – China
- DEG in Cough syrup - Panama
- DEG in toothpaste – China
- Cantaloupes – Honduras
- 5 types of aquacultured fish – China
- Innumerable adulterated “dietary supplements” – China

Main Lessons Learned

- **FDA – To do our job more effectively at home, we've got to do our job more efficiently abroad. Build on the foundation we had established.**
- **Industry – Its "brand" reputation is dependent on the quality of suppliers with whom they choose to engage.**
  - **Both individual corporate and industry-wide "brands"**
- **Consumer – When it comes to food and drugs, maybe cheapest isn't the most desirable attribute.**

Main Lessons Learned

- **All – In the world of sourcing our food and drugs, we're not in Kansas anymore – it's a GLOBAL SUPERMARKET – and Americans are shopping everywhere.**

- **In 2007, the United States imported more than $2 trillion worth of FDA-regulated products, from roughly 200 countries or territories, using 825,000 importers, through over 300 U.S. ports–of-entry.**

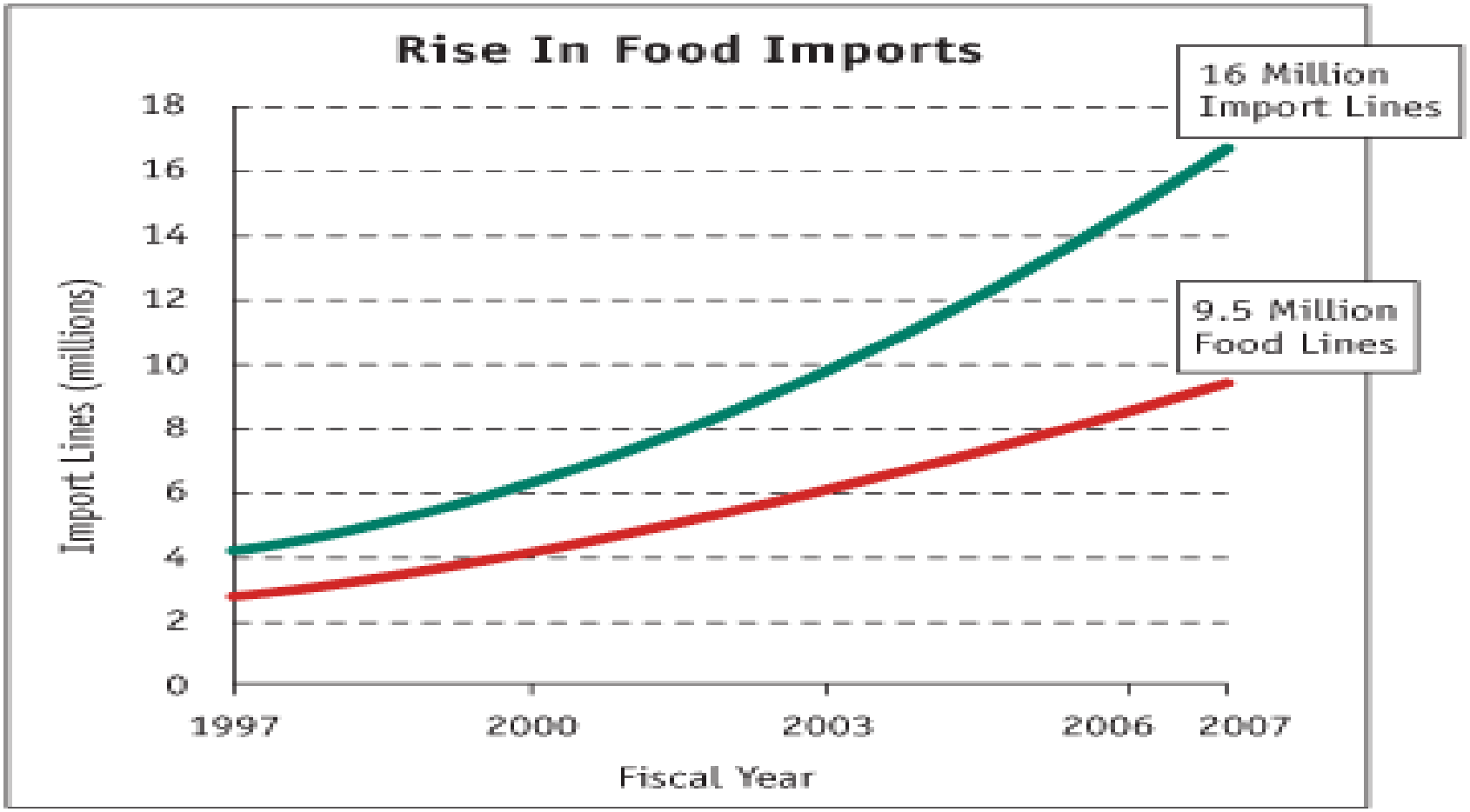
Challenges of Globalization

Globalization has fundamentally changed the environment for regulating food and medical products

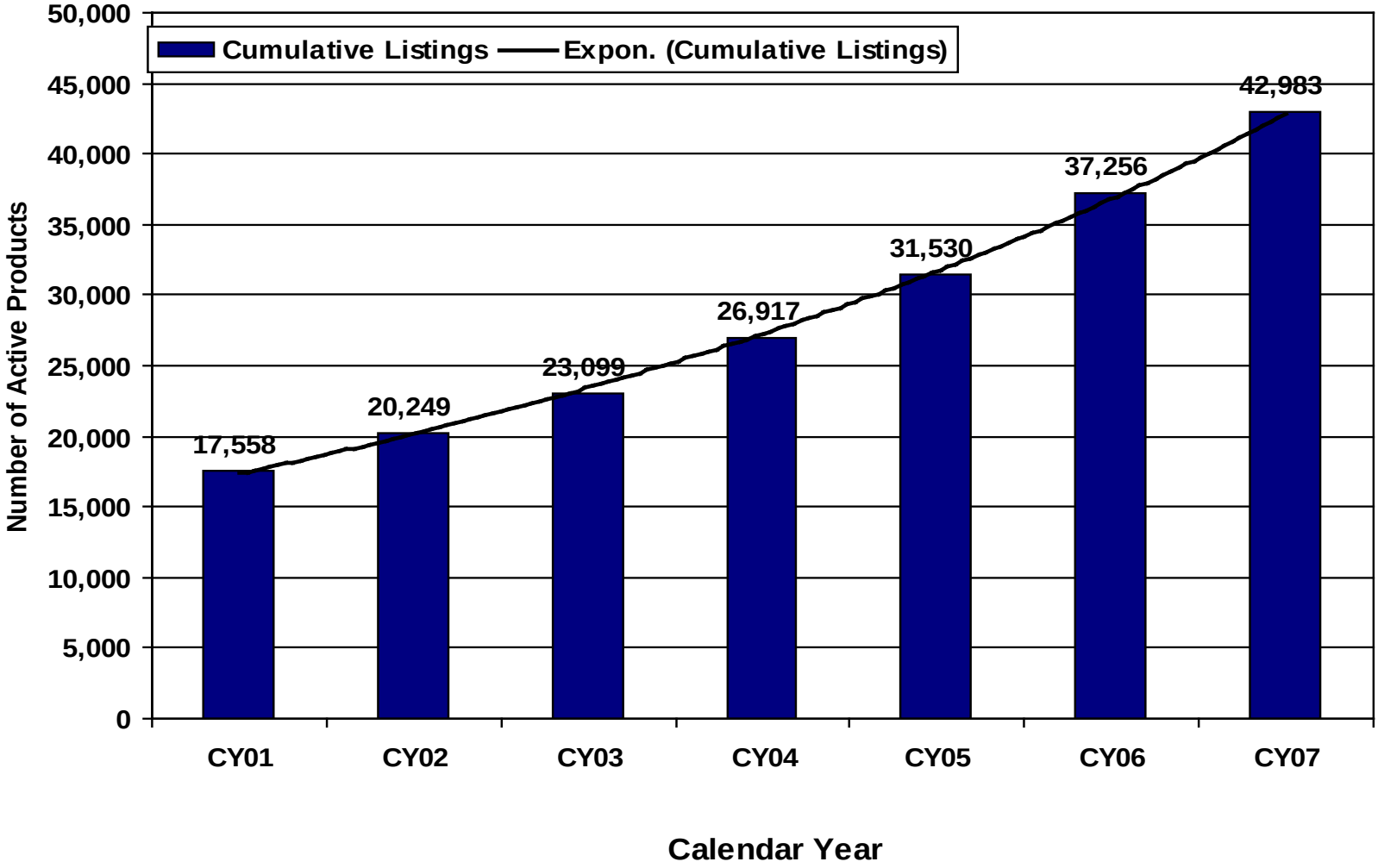
Created unique regulatory challenges for FDA:

- **More foreign facilities supplying the U.S.;**
- **Increasing volume of imported products;**
- **More outsourcing of manufacturing and clinical trials;**
- **Greater complexity in supply chains;**
- **Growing complexity of products and manufacturing methods;**
- **Imports coming from countries with less well developed regulatory systems; and**
- **Greater opportunities for economic fraud.**

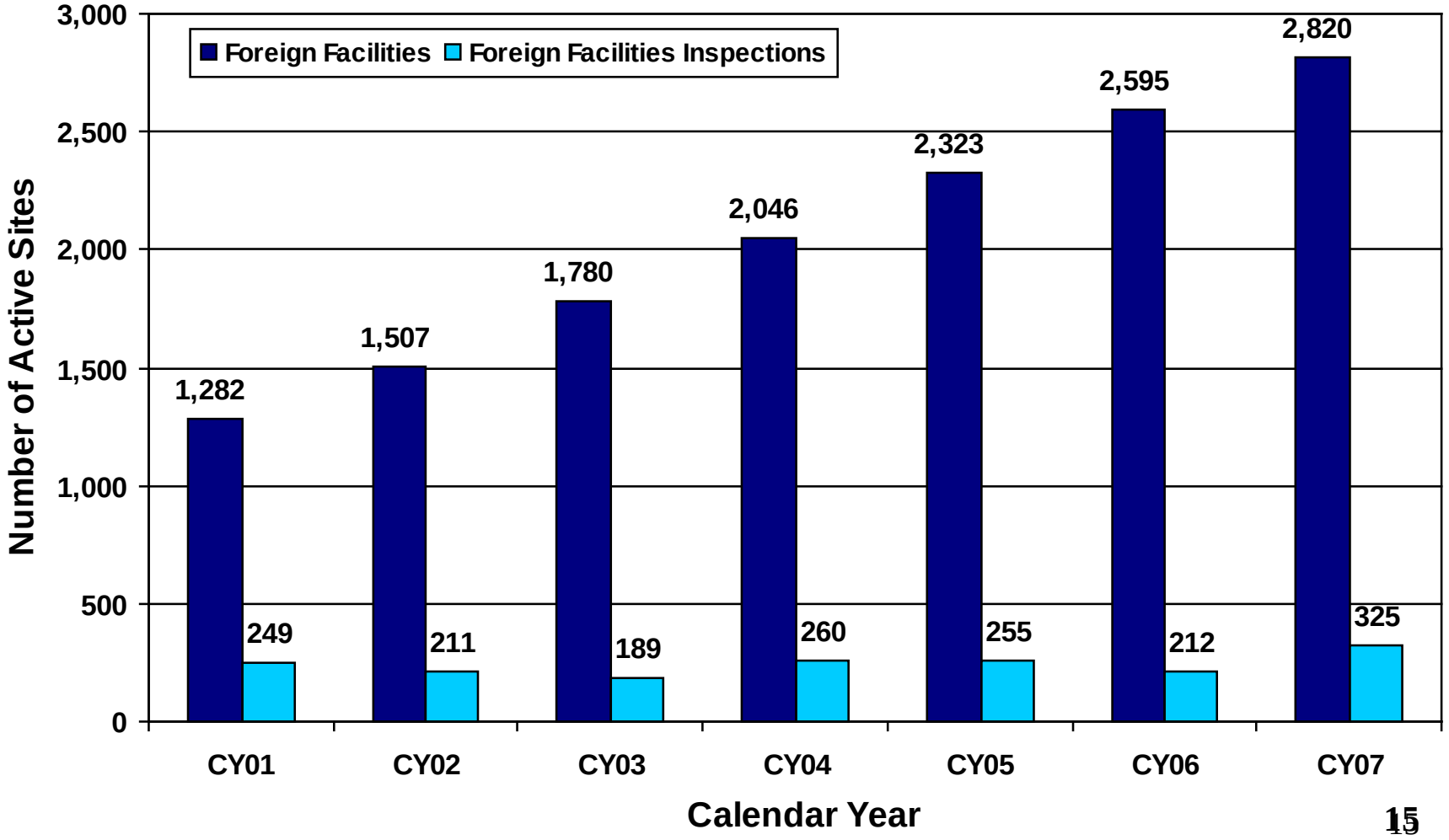
GLOBAL SUPERMARKET



Number of Drugs* Manufactured at Foreign Sites Has More Than Doubled Since 2001



Number of Foreign Sites Making FDA-Regulated Drugs Has More Than Doubled Since 2001.



Multiple Challenges

- **Some of these products come from countries with governments that do not wish us well**

- **Some come from countries with little ability to provide the regulatory oversight needed to assure the safety of products exported from their country.**

Multiple Challenges

- **Lax oversight in many foreign locales presents opportunities for contamination, counterfeiting, or economic “gain” by cutting corners**

- **Food, cosmetics, and medical products could all be used as unsuspected offensive weapons against a large part of the US or any other country’s population**

21st Century Reality

- Borders can no longer be the first line of defense
- We can no longer “inspect” out bad products at the border
- Borders must be places where we “audit” that indeed quality has been built in at the point of manufacture

21st Century Reality

- **We must:**

Engage more effectively abroad in order to be more effective at home

The Response

- **FDA Global Presence**
  - **Continued bilateral and multilateral engagement with trusted counterparts**
    - **International Standards Development and Harmonization**
    - **Foreign Inspections – cadre and individual volunteers**
    - **Receive and Use Inspection Reports from trusted foreign counterpart authorities**
    - **Third Party Certification**
  - **24/7 Presence in Strategic Areas**

Present In-Country Focus

Better Information

- Through several broad initiatives, many of which are specific to certain areas, obtain better and more robust information to help FDA officials in the centers and at the borders make better decisions about the products:
  - that are being developed for the US market,
  - that are being reviewed for marketing authorization in the USA,
  - that are being presented for entry into the US, and
  - that are presently already on the US market.

FDA Global Presence: Activities

- **(1) Working with counterpart agencies in-country, gather better knowledge about the production of these products and their transport to US ports**

- **(2) Engage with *trusted* counterpart agencies overseas to leverage scientific, inspectional, and other resources**

FDA Global Presence: Activities

- **(3) When requested, engage with *developing* counterpart agencies to help build their capacity**

- **(4) Engage private- and public-sector *trusted third parties* to provide helpful information about regulated industry compliance with FDA standards**

FDA Global Presence: Activities

- **(5) Engage with *regulated industry* to provide greater information about expectations and standards for their products to be admitted to the USA**

- **(6) Engage with *USG agencies already in-country* with complementary missions**

FDA Global Presence: Activities

- **(7) Have the capacity to perform *more overseas inspections of high risk facilities***

RESULT: Must be assured that products meet our standards BEFORE they reach our ports

- ***Point of manufacture, point of export, in transit, and when presented for importation***

FDA Global Presence
Initial In-Country Locations

- China
- India
- Latin America
- Europe
- The Middle East

Current FDA Foreign Locations Status

- China: Posts officially opened in Nov 2008.
  - Beijing
    - Director; Sr Tech Experts in foods, medicines, and medical devices
  - Guangzhou
    - 2 inspectors (foods expertise)
  - Shanghai
    - 2 inspectors (medicines expertise)
  - Local hires in all three posts (n=5)

Current FDA Foreign Locations Status

- India: Post in New Delhi opened Jan ’09 Mumbai opened later in year.
  - New Delhi
    - Director, Sr Technical experts in medicines, medical devices, and foods
  - Mumbai
    - Inspectors (foods and medicines expertise)
  - Local hires in both posts

Current FDA Foreign Locations Status

- **Latin America: Post San José, Costa Rica opened in Jan ’09; Posts also in Mexico City, and Santiago.**
  - **San Jose**
    - **Director, Sr technical experts in laboratory medicine and foods**
  - **Mexico city**
    - **Sr technical experts in foods and medicines**
  - **Santiago**
    - **Sr Technical expert in foods**
  - **Local hires at each post**

Current FDA Foreign Locations Status

- **Europe: Main location in Brussels opened in Dec ’08; sr tech expert in medicines located at European Medicines Agency in London, and sr tech expert in foods located at European Food Safety Agency in Parma.**

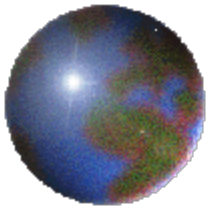
- **Middle East: Locations under discussion with US State Department**
  - **Director and Sr technical expert in medicines on board. Sr technical expert in foods to be selected. Inspector to be selected.**

Current FDA Foreign Locations Status

Total: 35 US nationals overseas

15 US nationals Rockville

19 Foreign nationals



THANK YOU

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