



# U.S. Food and Drug Administration

American Spice Trade Association

October 18, 2007

William K. Hubbard



# Overview Briefing

- Background on FDA
- Responsibilities
- Budget shortfalls
  
- Two biggest challenges
  - - Food Safety
  - - Imports



# Fast Facts About FDA

- Science-Based Regulatory Agency
- Organized by Product Area
- 18 Locations, 40 buildings in Washington Area
- 207 Field Offices Around U.S.
  - 13 Field Laboratories
- 10,124 Employees
- Physicians, Pharmacologists, Toxicologists, Microbiologists, and Other Scientific Professionals
- \$ 2 Billion Budget

# Scope of FDA'S Mission

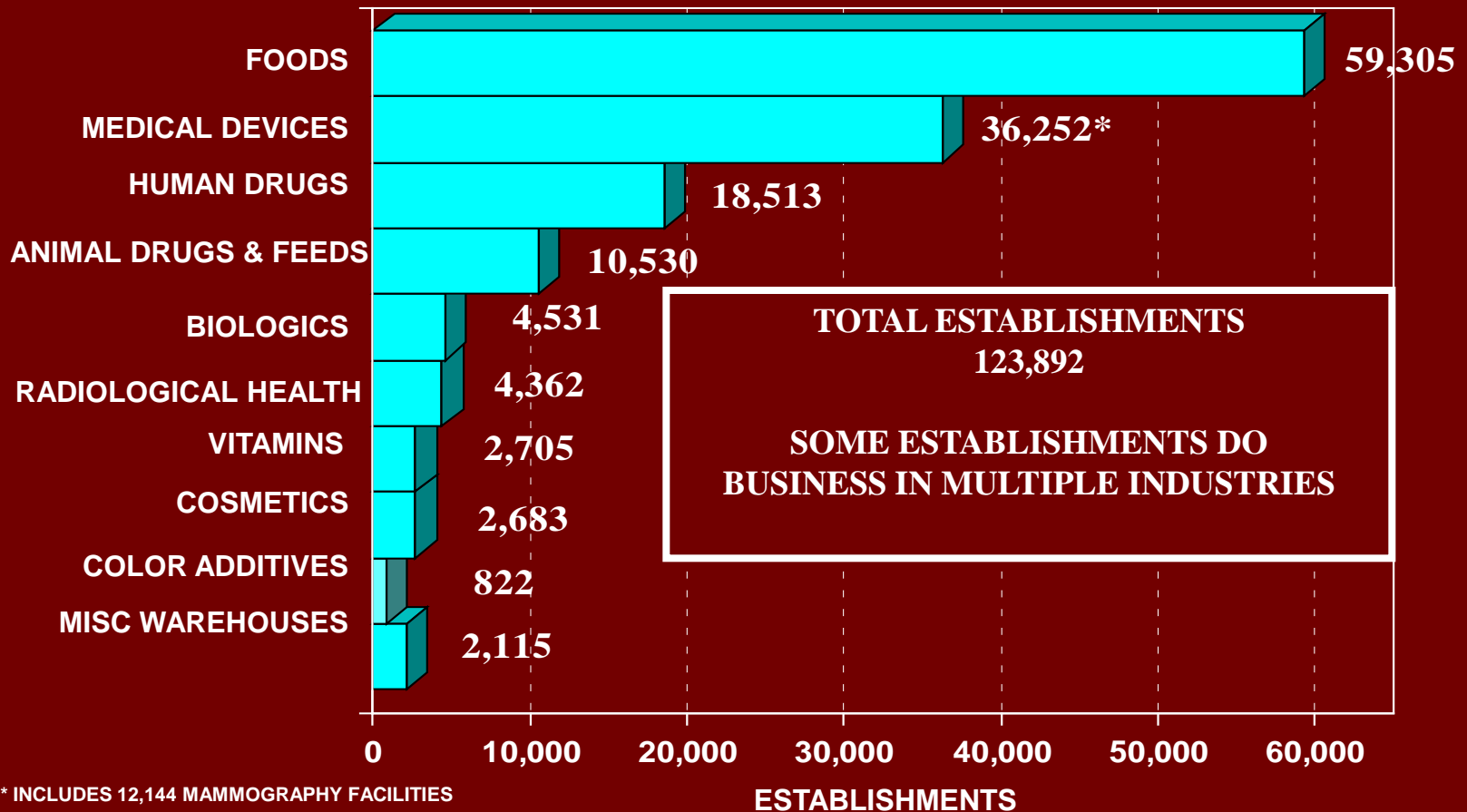
- Food
- Drugs
- Vaccines/Blood
- Dietary Supplements
- Animal Foods & Drugs
- Toxicological Research
- Biotechnology
- Medical Devices/  
Radiological Products
- Cosmetics



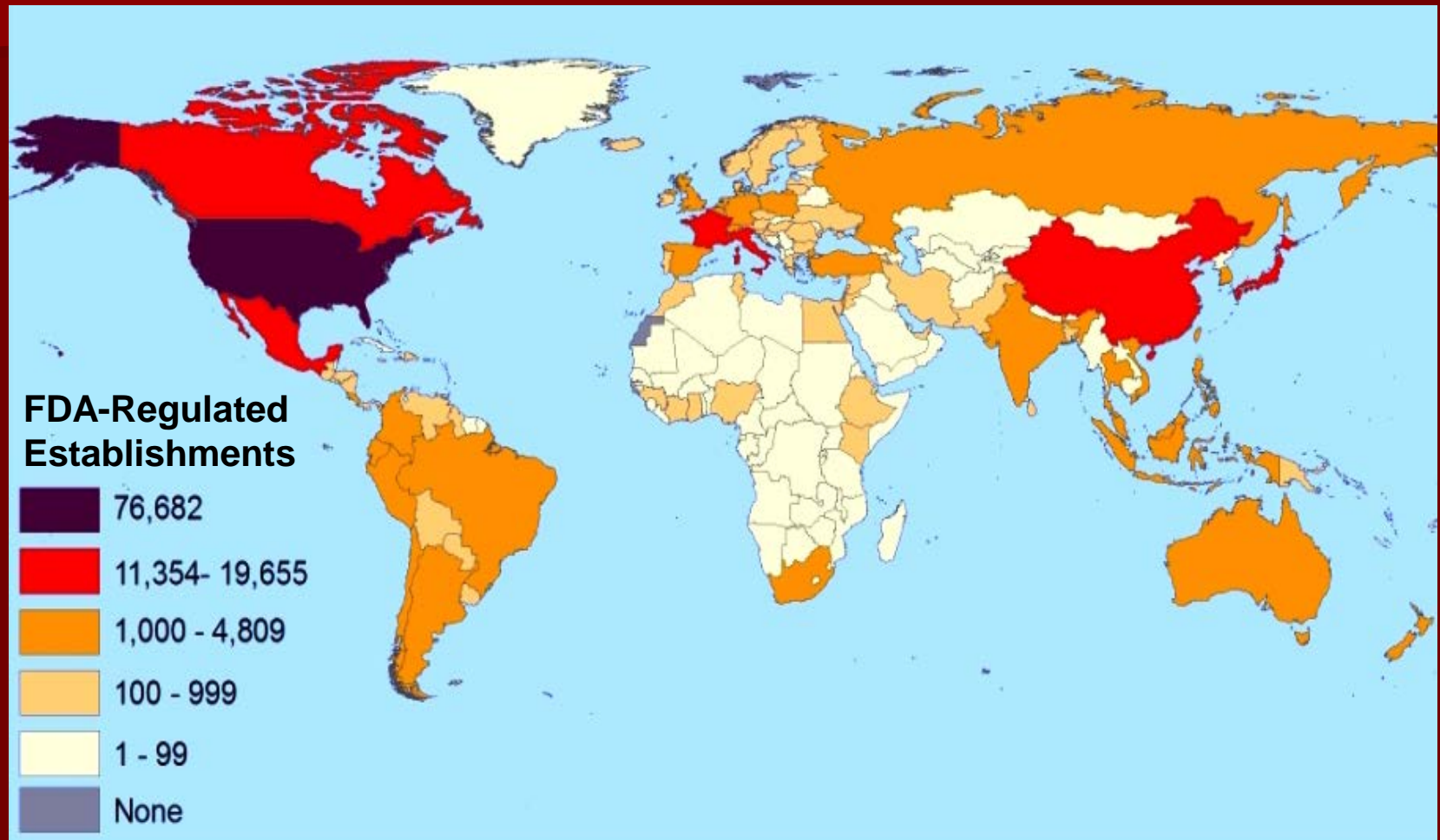


# Domestic Industry is Huge

## Establishments under FDA's Regulatory Authority



# FDA covers over 375,000 Establishments Worldwide



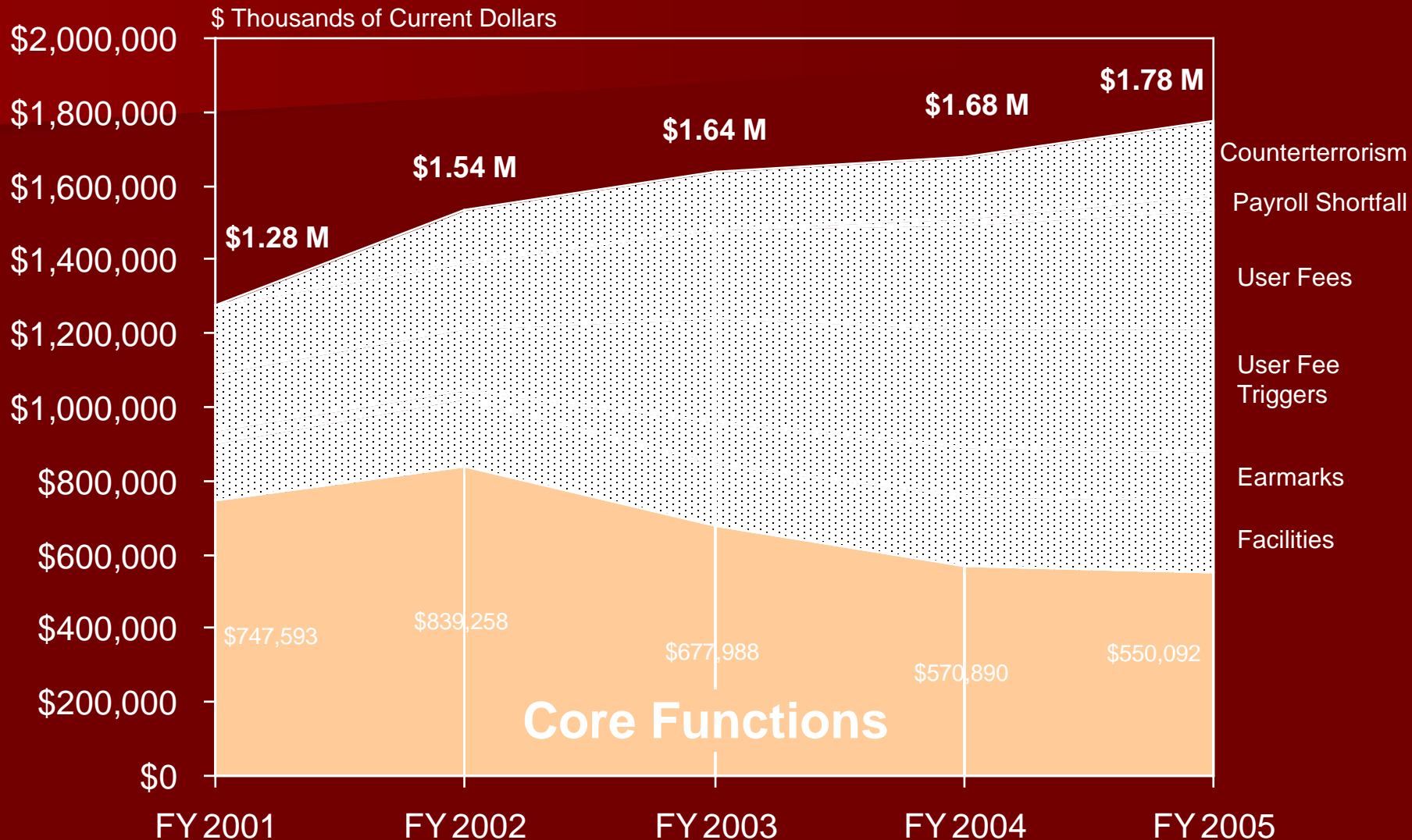




# Congress keeps adding responsibilities

1907 - Federal Meat Inspection Act	1994 - Animal Medicinal Drug Use Clarification Act	1999 - Government Employees Training Act
1914 - Federal Trade Commission Act	1994 - Dietary Supplement Health and Education Act	1999 - Fed. Financial Assistance Management Improvement Act
1923 - Filled Milk Act	1995 - Federal Reports Elimination and Sunset Act	2000 - Responsible for Clinical Laboratory Improvement Amendments (CLIA)
1927 - Import Milk Act	1995 - Unfunded Mandates Reform Act	2000 - Approps Act (FDA) - FY 2001
1944 - Public Health Service Act	1995 - The Paperwork Reduction Act	2000 - Medicine Equity and Drug Safety Act
1946 - Trademark Act of 1946	1996 - Freedom of Information Act (FOIA)	2000 - Prescription Drug Import Fairness Act
1953 - Reorganization Plan 1	1996 - Safe Drinking Water Act Amendments	2000 - Approps. Act (HHS) Sec. 516, HPV-Condom Labeling Review
1957 - Poultry Products Inspection Act	1996 - Animal Drug Availability Act	2000 - Ryan White AIDS Care Act
1966 - Fair Packaging and Labeling Act	1996 - Food Quality Protection Act	2000 - Date Rape Drug Prohibition Act
1968 - Radiation Control for Health & Safety Act (RCHSA)	1996 - Economic Espionage Act of 1996	2000 - Children's Health Act
1970 - The National Environmental Policy Act	1996 - Electronic Freedom of Information Improvement Act	2000 - Technology Transfer Commercialization Act
1970 - Controlled Substances Act	1996 - Comprehensive Methamphetamine Control Act	2001 - Animal Disease Risk Assessment
1970 - Controlled Substances Import and Export Act	1996 - Health Insurance Portability and Accountability Act (HIPAA)	2002 - Medical Device User Fee and Modernization Act (MDUFMA)
1970 - Egg Products Inspection Act	1996 - Drug-Induced Rape Prevention Punishment Act	2002 - Hatch-Waxman-Amendments
1971 - Lead-Based Paint Poisoning Prevention Act	1997 - Food & Drug Administration Modernization Act (FDAMA)	2002 - Drug Importation Report
1972 - Federal Advisory Committee Act	1997 - Better Pharmaceuticals for Children Act	2002 - Farm Security & Rural Investment Act
1976 - Government in the Sunshine Act	1997 - PDUFA II	2002 - Bioterrorism Act
1976 - Food, Drug and Cosmetic Act (FD&C)	1998 - Antimicrobial Regulation Technical Corrections Act	2002 - PDUFA III
1980 - Infant Formula Act	1998 - Sec. 615 Ag. Research, Extension and Education Reform Act	2002 - Best Pharmaceuticals for Children Act
1980 - Government Patent Policy Act of 1980	1998 - MQSA Reauthorization	2002 - Rare Diseases – Orphan Product Development
1983 - Federal Anti-Tampering Act	1998 - Sec. 654, Omnibus Approps. (Family Impact Assessments)	2002 - E-Government Act
1983 - Orphan Drug Act		2003 - Mosquito Abatement for Safety and Health Act
1984 - Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act)		2003 - Animal Drug User Fee Act
1987 - Prescription Drug Marketing Act (PDMA)		2003 - Pediatric Research Equity Act (PREA)
1988 - Generic Animal Drug and Patent Term Restoration Act		2003 - Medicare Prescription Drug and Modernization Act
1990 - Safe Medical Devices Act (SMDA)		2004 - Minor Use and Minor Species Animal Health Act
1990 - Nutritional and Educational Labeling Act (NLEA)		2004 - Food Allergen Labeling and Consumer Protection Act
		2004 - Medical Devices Technical Corrections Act
		2004 - National Defense Authorization Act
		2004 - AIDS (PEPFAR)
		2004 - Project BioShield
		2004 - Anabolic Steroid Control Act
		2004 - MQSA Reauthorization
		2004 - Homeland Security Presidential Directive (HSPD) #12, Identification Standard
		2005 - Protecting America in the War on Terror Act
		2005 - Patient Safety & Quality Improvement Act
		2005 - Medical Device User Fee Stabilization Act (MDUFSA)
		2005 - Stem Cell Therapeutic and Research Act
		2006 - Combat Meth Act

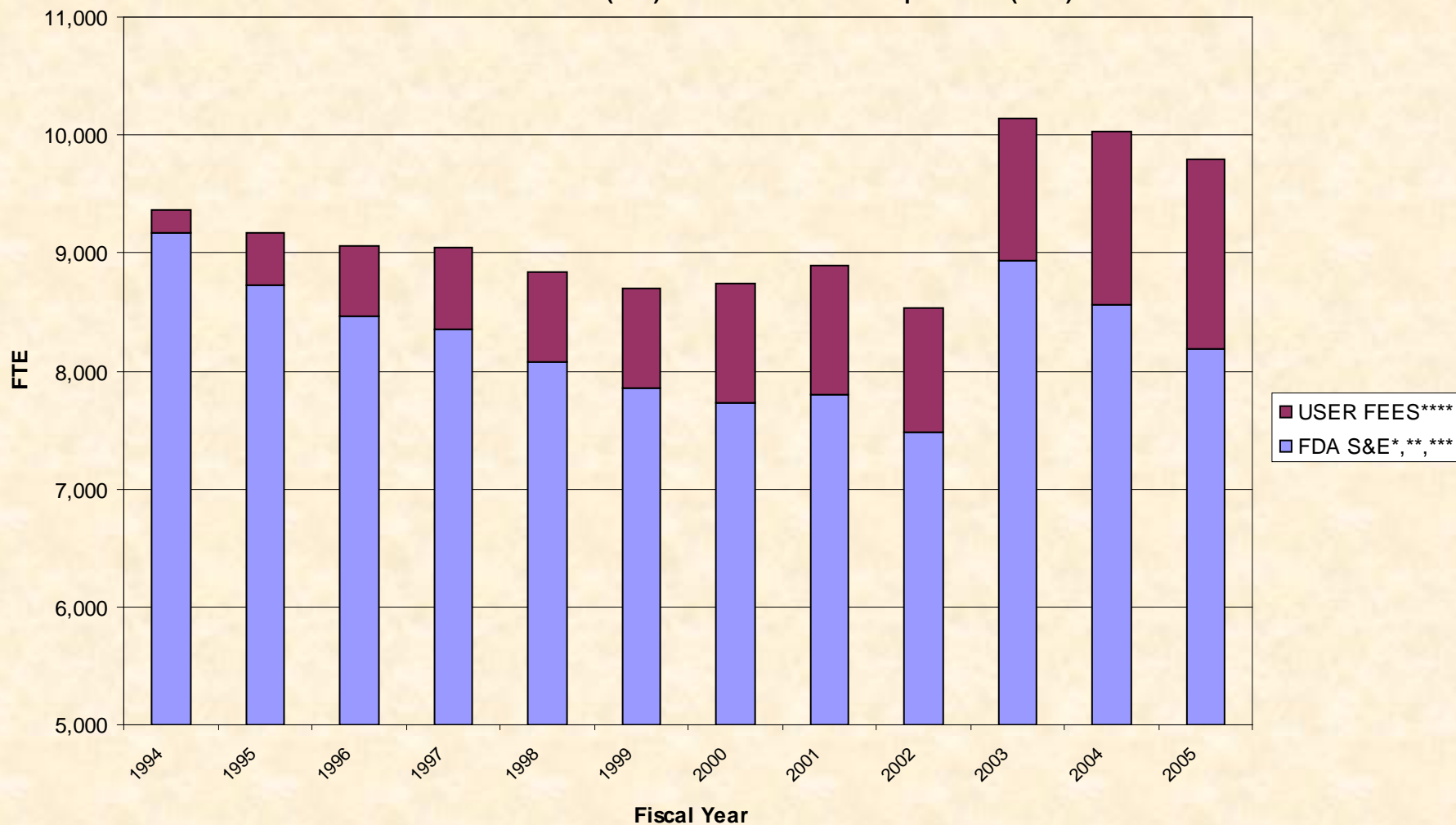
# FDA Budget Picture Since 2001





# FDA Staffing

**Food and Drug Administration**  
Full Time Permanent (FTP) Positions / Full Time Equivalents (FTEs)



\* Prior to 1980, FDA counted each federal employee as a Full Time Permanent (FTP) position.

\*\* Listed are program level FTPs or FTEs only. User Fees, Revolving Fund for Certification and Other Services, Advances & Reimbursable, and Parklawn Computer Center FTPs or FTEs are NOT included in the FDA S&E column.

\*\*\* Source: DHHS/FDA Justification of Estimates for Appropriations Committees

\*\*\*\* Source: FDA's data submission to Bio and PhRMA PDUFA IV information request: Source: MDUFMA Industry Chart: Source: ADUFA Industry Chart

# Annual Budget Requests

- Never include the full cost to FDA of the increased costs of pay and benefit increases
- Never include increases for increased non-pay costs
- Almost always include reductions in FDA's budget under a variety of headings
  - Administrative Savings
  - IT Consolidation
  - Strategic Redeployment, etc....

# Appropriations for Food

## FDA Foods Appropriated Budget Authority, If...

1. Appropriated Budget Authority had increased at 5.8% per year over FY 2003 level, and
2. All funds for program increases had really been added to the Appropriation

*Dollars in Millions*

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Amt if 2003 increased by 5.8% per year	\$ 407	\$ 430	\$ 455	\$ 482	\$ 510

Additions Shown in Budget, and then increased in Subsequent years at 5.8%

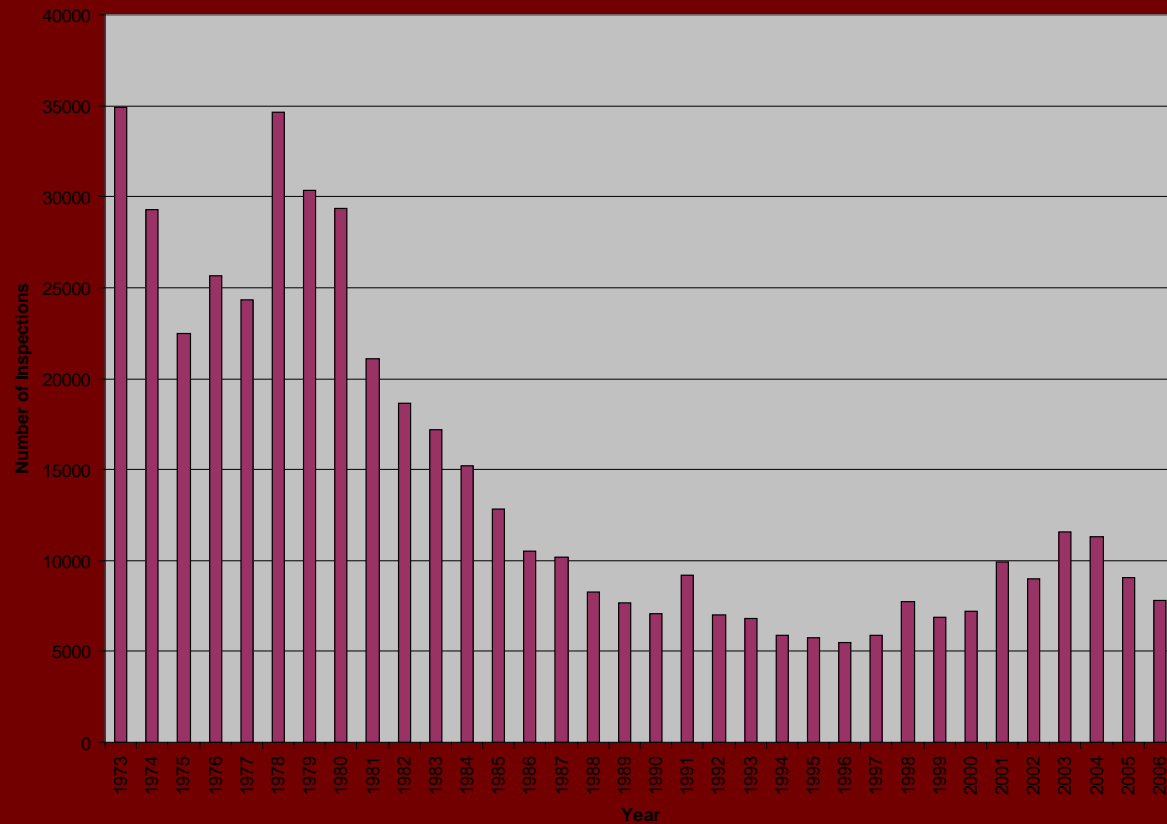
1) Counterterrorism--Food Safety		\$ 20.5	\$ 21.7	\$ 22.9	\$ 24.3
2) Food Defense--Counterterrorism			\$ 60.8	\$ 64.3	\$ 68.0
3) Food Defense				\$ 4.8	\$ 5.1
4) Food Defense					\$ 18.4

Total Additions		\$ 21	\$ 82	\$ 92	\$ 116
What would have been:	\$ 407	\$ 451	\$ 538	\$ 574	\$ 626
Actual Appropriation: <sup>1</sup>	\$ 407	\$ 407	\$ 436	\$ 439	\$ 450
Difference		\$ (44)	\$ (102)	\$ (135)	\$ (176)
Percent Difference		-10%	-19%	-24%	-28%

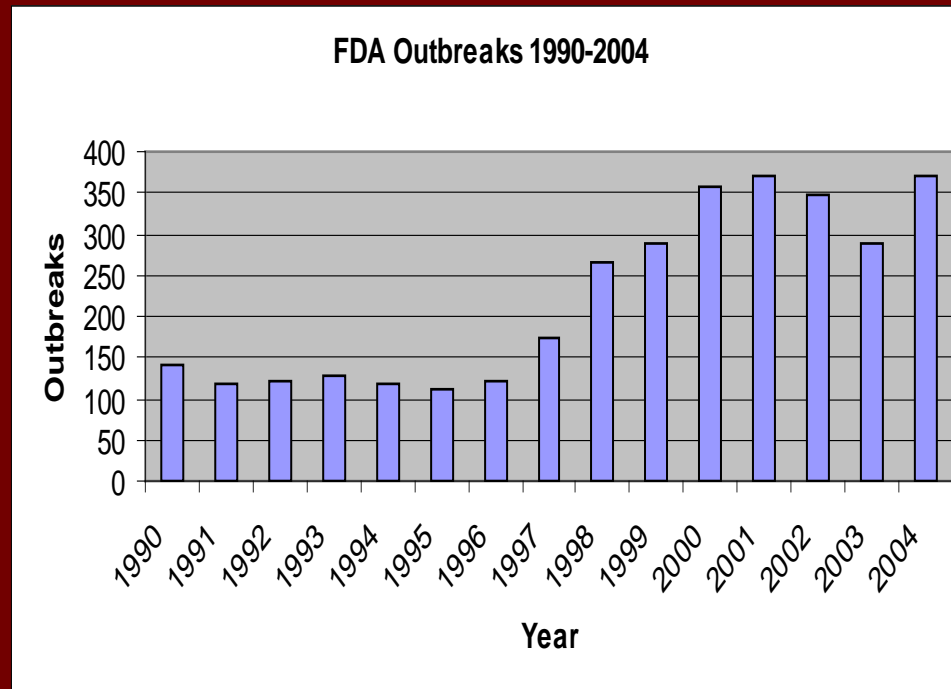
<sup>1</sup> From S&E Budget Authority in All Purpose Tables in Congressional Budget Justifications

# Food Inspections 1973-2006

FDA Inspections (1973-2006)



# Foodborne Disease Outbreaks



# Example of Impact

- Spinach – 2006
  - E Coli 0157:H7
  - 205 cases, many hospitalizations, 3 deaths
  - Severe bloody diarrhea, cramps
    - HUS – Red blood cells destroyed, kidney failure, death
- Weeks of investigation to find source
- What to Say at the Beginning?



# Only Possible Message

- "Don't eat spinach"
- Weeks later, 3 California farms implicated
- Nationwide spinach crop wrecked
- \$100M in economic costs





# Public Confidence Plummeting

## Harris Poll:

	Fair/poor job	Excellent/good job
2000	37%	61%
2004	47%	56%
2006	58%	36%

# Imports of FDA-Regulated Products



# Problems with Imported Foods

- Illegal animal drugs
- Filth
- Bacterial contamination
- Unapproved additives
- Pesticide residues
- Heavy metals
- Fraudulent substitution
  - Melamine
  - Inulin

# Problems, continued

- Increasing sourcing from developing countries w/o regulatory structures
- No systemic food production standards
- Allegations of "dumping"
- Governments focused on economic development (looking the other way)
- Cottage industries feeding into larger distributors
- Non-Western business practices

# Chinese flour processor





# What's the Solution?

- Private sector management of supply chain
- Improved standards and oversight in the exporting country
- Improved international standard setting
- Improved FDA oversight and enforcement



# What would FDA Do?

## (In a prevention-focused system)

- Set requirements for industry to develop preventive measures
- Establish performance standards for accountability
- Enforce standards (e.g., inspections)





# GMA/FPA "4 Pillars"

- Importer accountability for prevention
- Use existing industry expertise in supply chain management
- Incentives for industry adoption of best practices
- Strengthen FDA to oversee prevention model

# President's Working Group

- Framework report issued 9/10
- Principles for upcoming action plan
  - 1) Build prevention in upstream
    - Focus on product life cycle, not just border inspection
  - 2) Intervene when risks are identified
    - Better technology, IT
  - 3) Respond rapidly after harm has occurred



# What's Next from Administration?

- Import action plan mid-November
- Domestic food safety proposals (October?)
- Work with Congress 2007-08
- 2009 budget released January 08

# Where is Congress?

- Many players (Dingell, Delauro, Waxman, Pallone, Durbin, Kennedy)
- Dingell bill – focus on user fees, border inspections
- Delauro – series of speeches
- Durbin – single food agency
- Pallone – HACCP-based
- Kennedy - drafting

# Imports – The Need

- New paradigm
- Shift responsibility from FDA border inspection to prevention:
- Responsibility/accountability across supply chain
- FDA resources to oversee , inspect foreign countries, develop new technologies



# Questions?