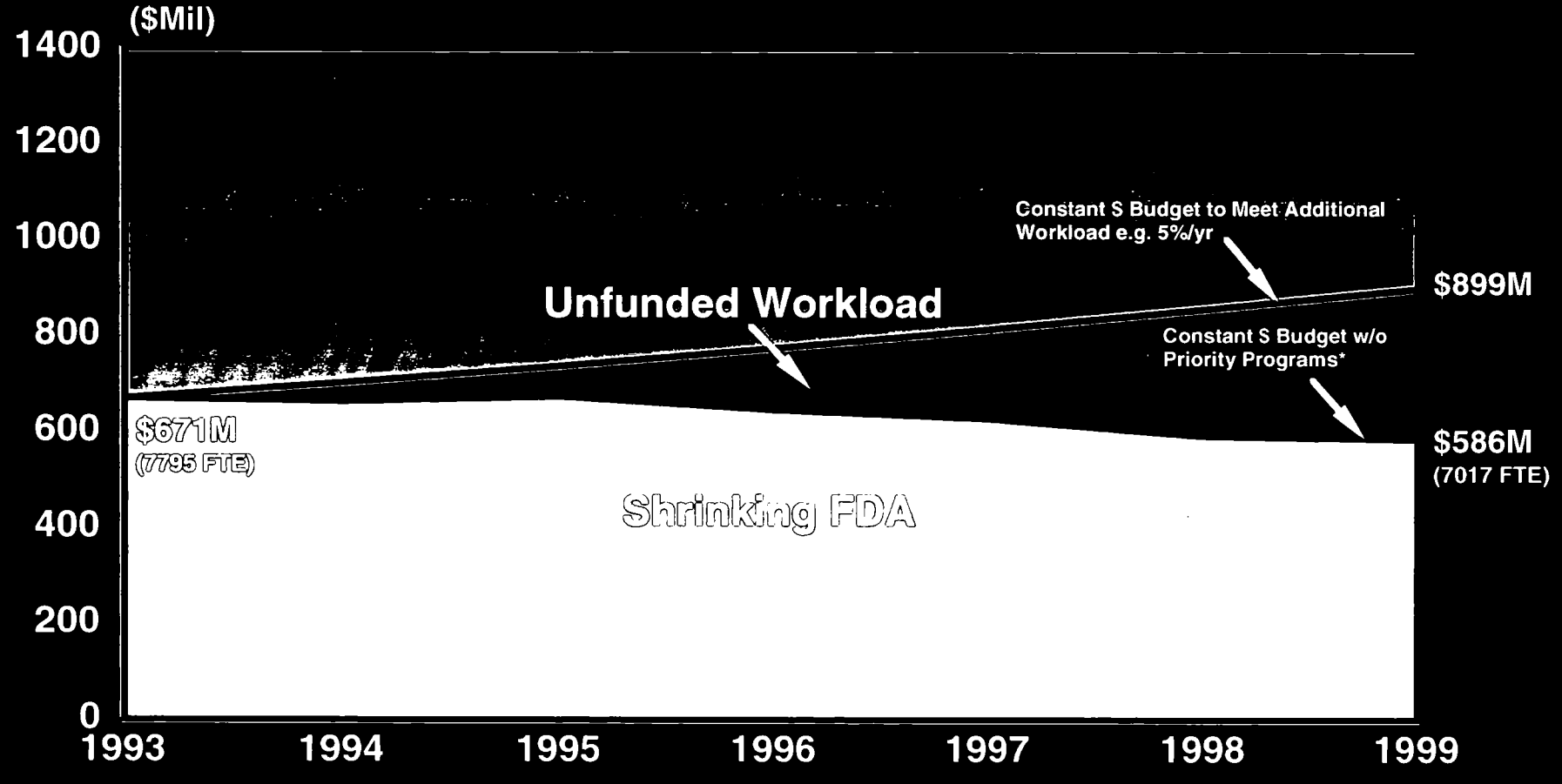
FDA - Ew

The Shrinking FDA

(Constant Dollar Effort Relative to Increasing Workload)



*Priority Programs = PDUFA, MQSA, Tobacco, and Food Safety Initiative.

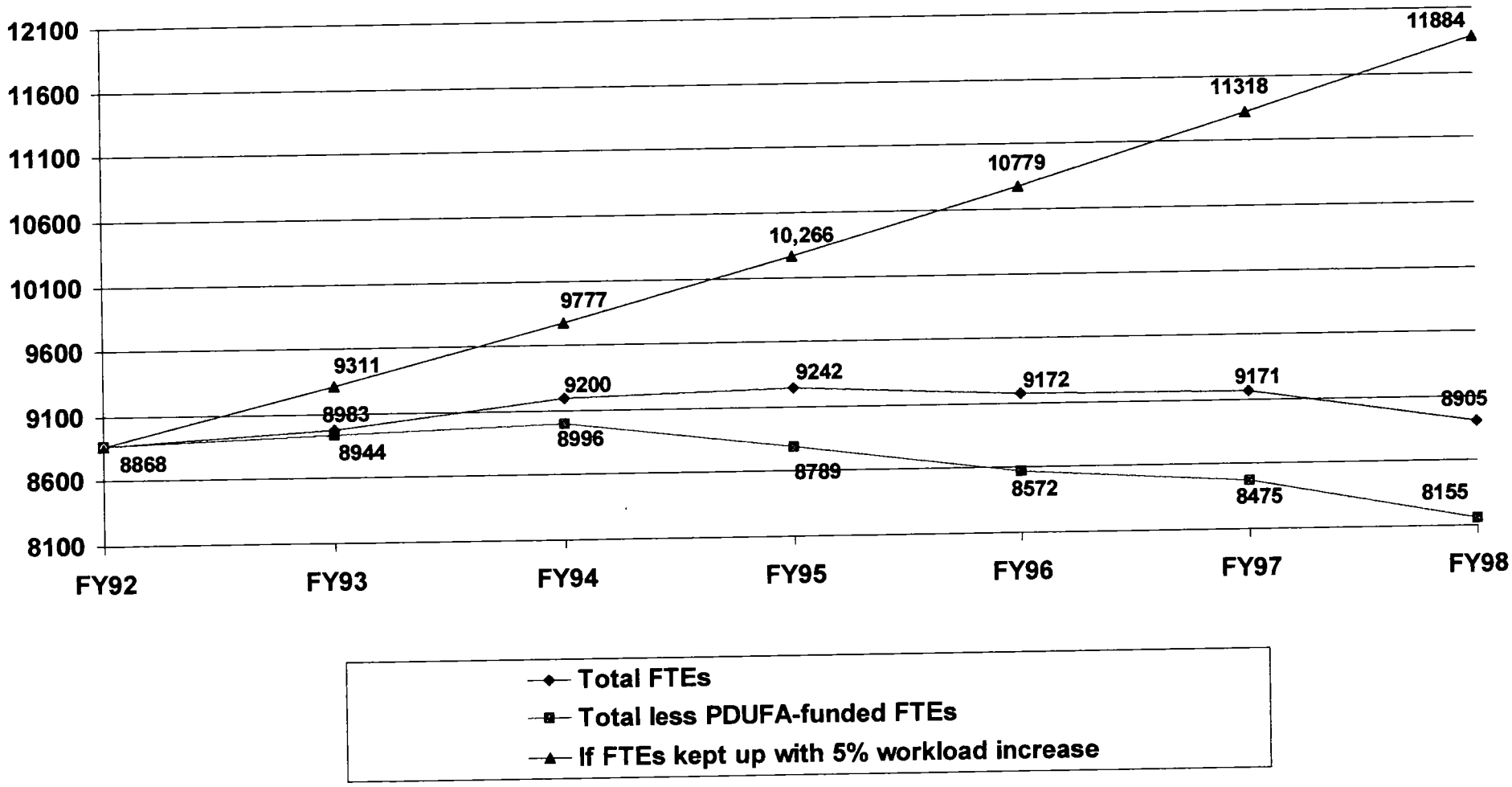
Declining Budgets

ABSORPTION OF CURRENT SERVICES WITHIN THE FDA BUDGET

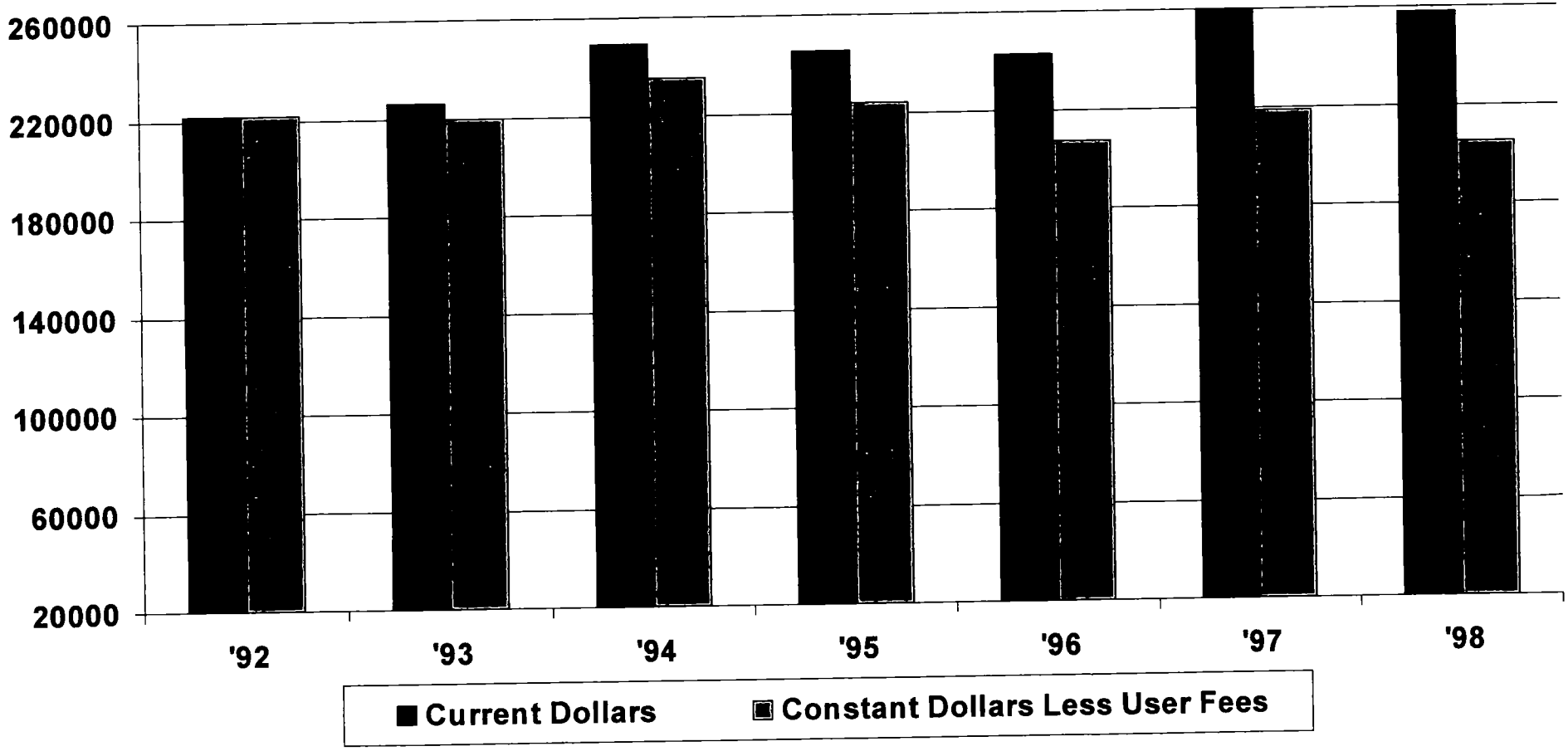
Dollars in Thousands

	FY 94	FY 95	FY 96	FY 97	FY 98	FY 99
Funds Needed to Maintain Previous Year's Level	$37,222	$33,529	$29,817	$33,430	$33,196	$31,657
Received from Congress	$15,000	$18,800	$0	$0	$0	$0
Effective Cut	($22,222)	($14,729)	($29,817)	($33,430)	($33,196)	($31,657)
Cumulative Effect	($22,222)	($36,951)	($66,768)	($100,198)	($133,394)	($165,051)

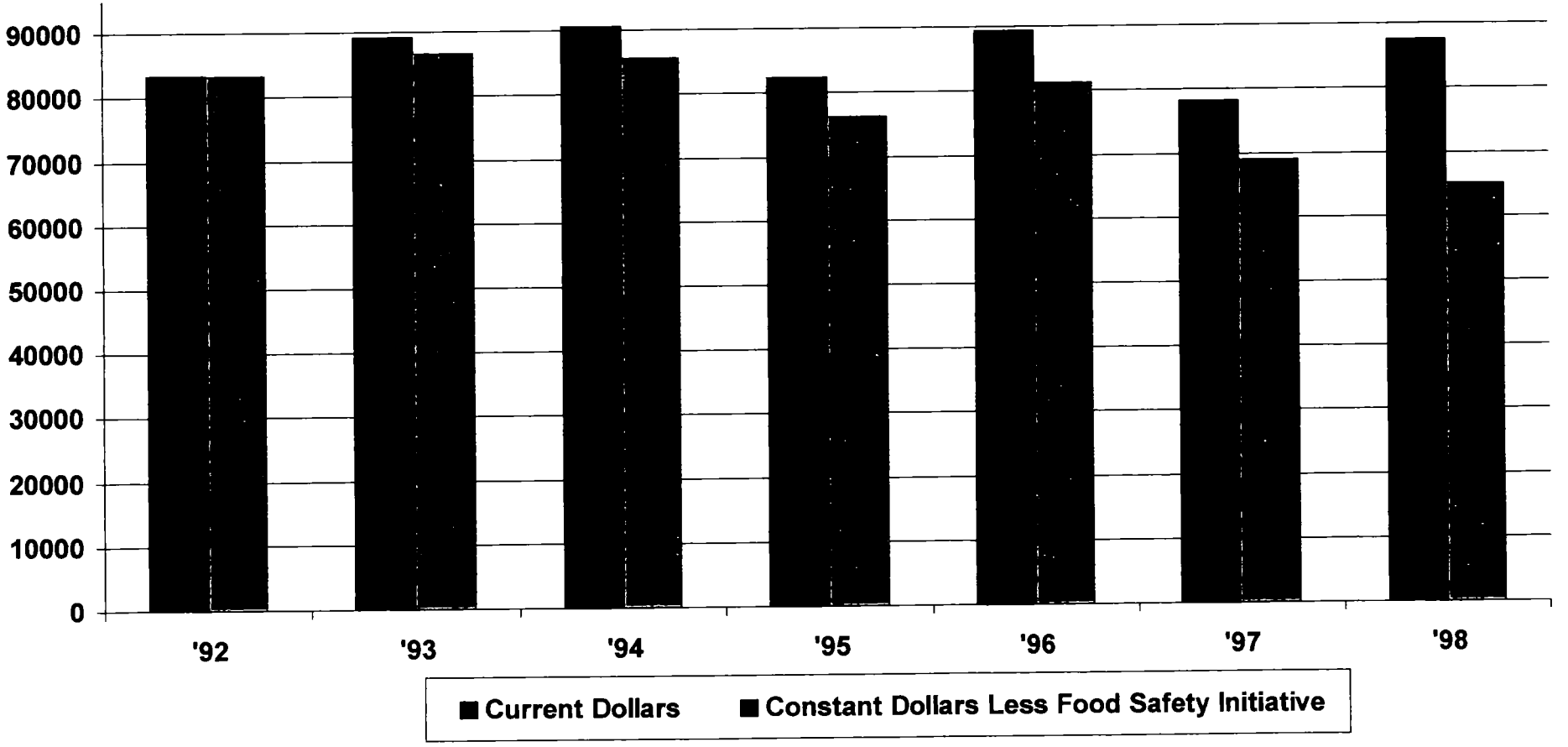
Food and Drug Administration FTEs



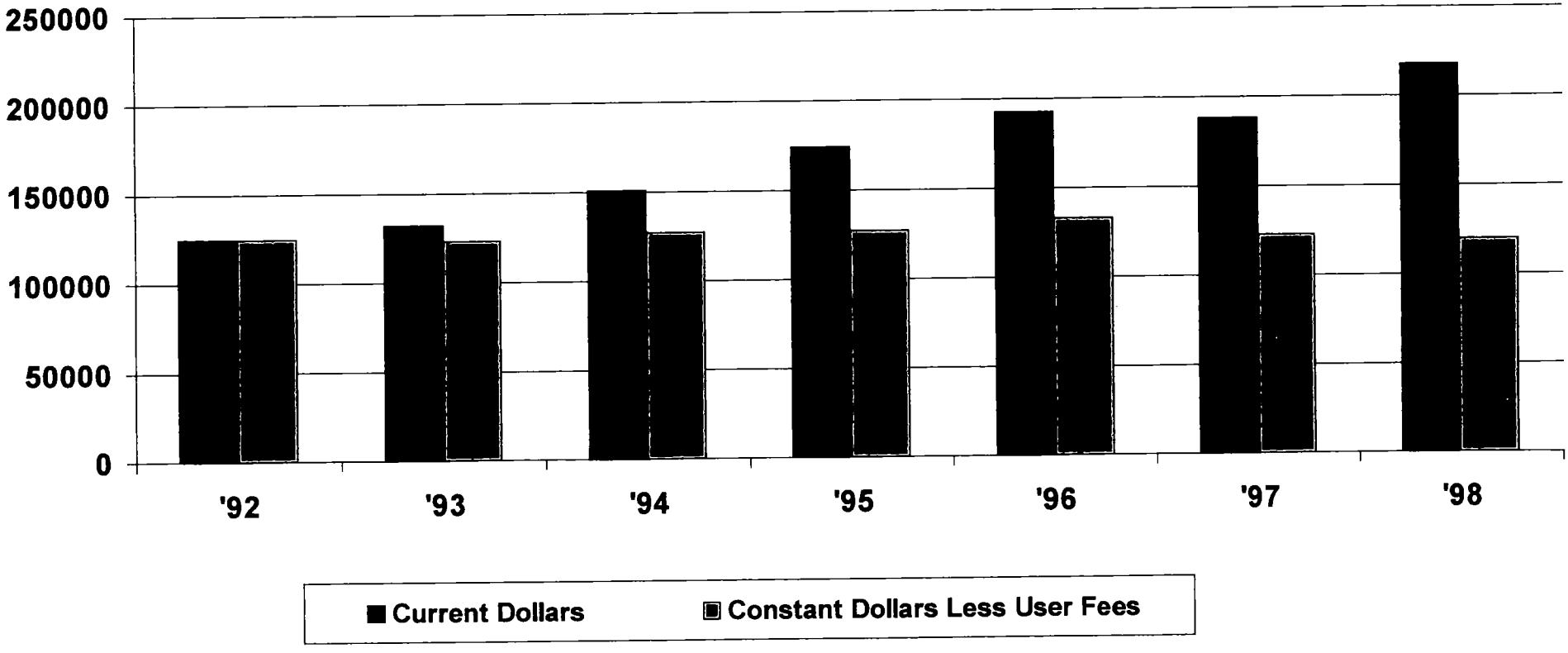
FDA'S INSPECTION RESOURCES*



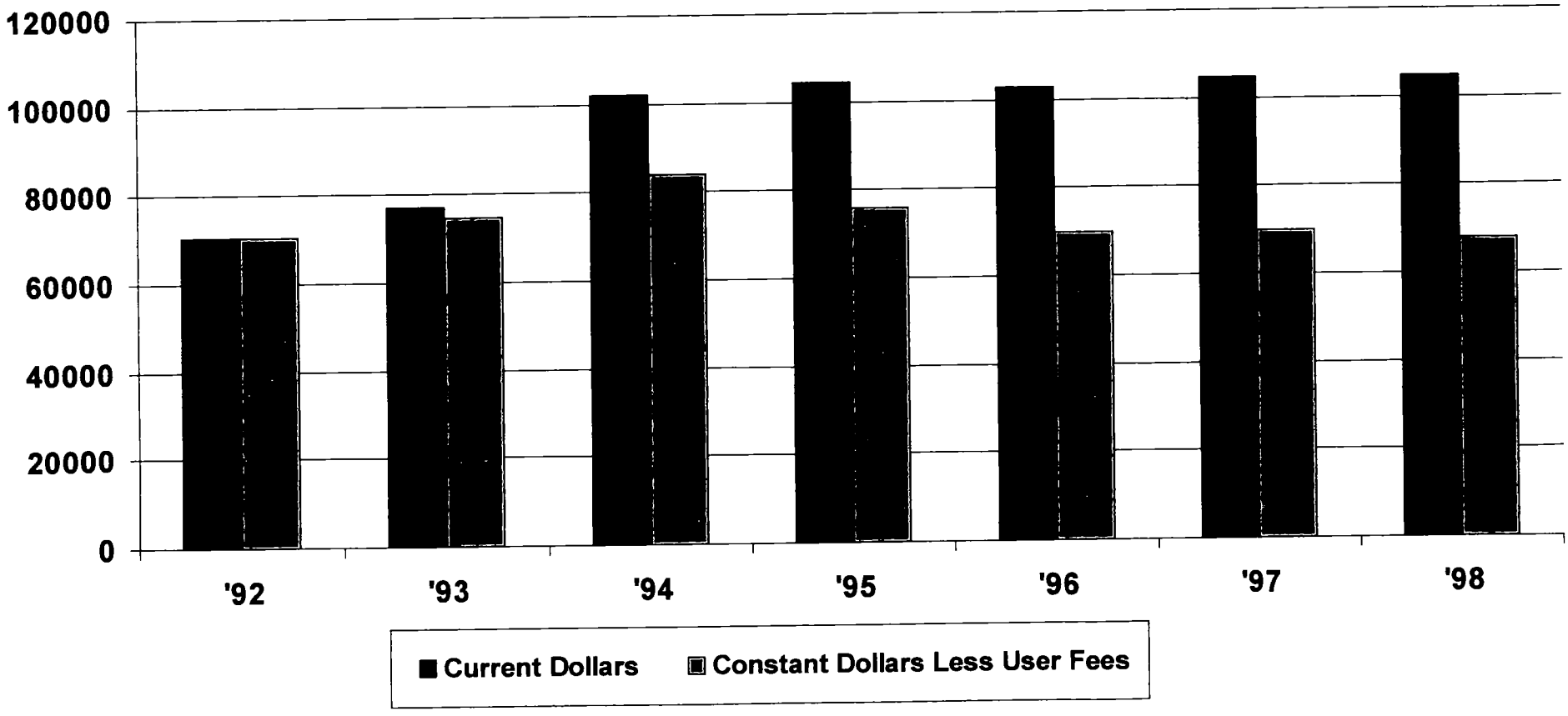
FDA'S FOOD RESOURCES*
(in millions)



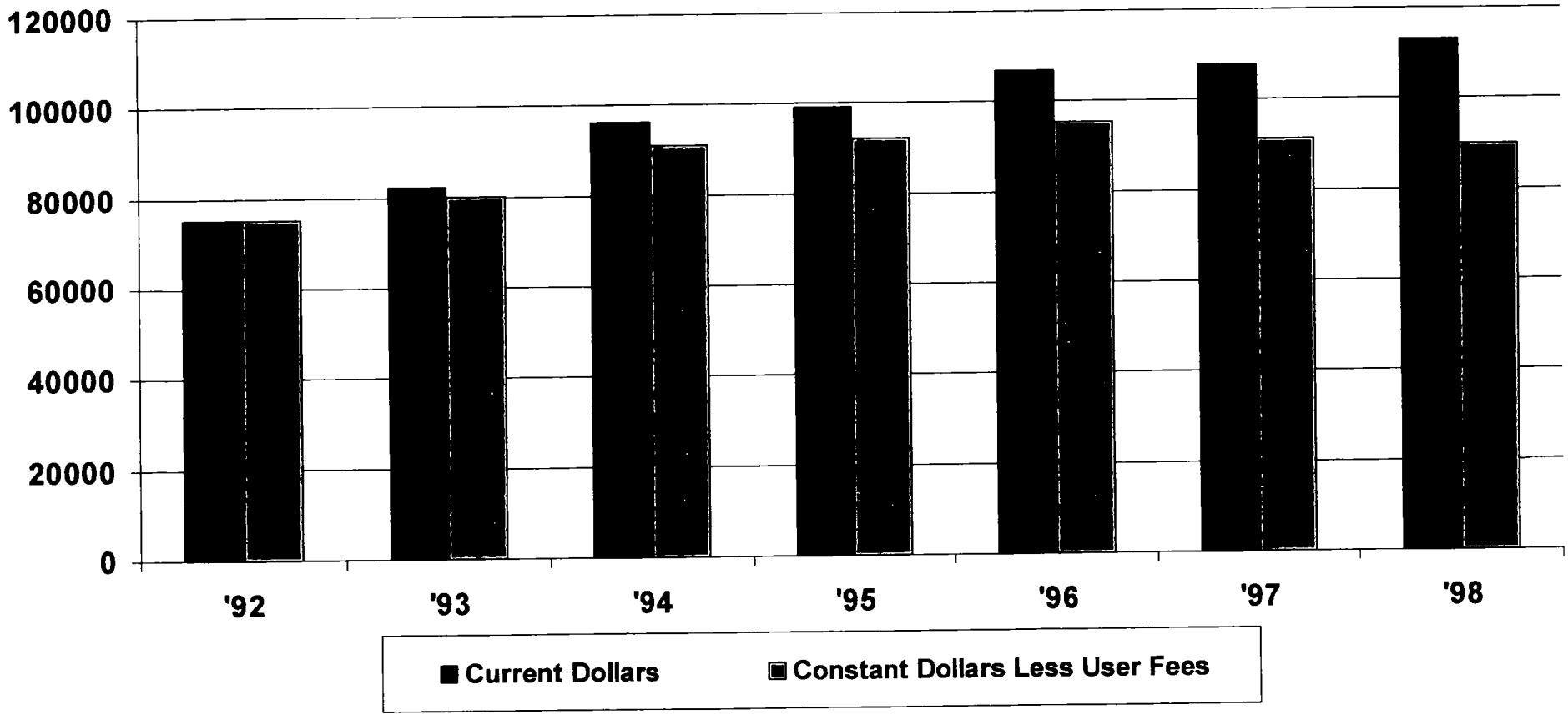
FDA'S DRUG RESOURCES*
(in millions)



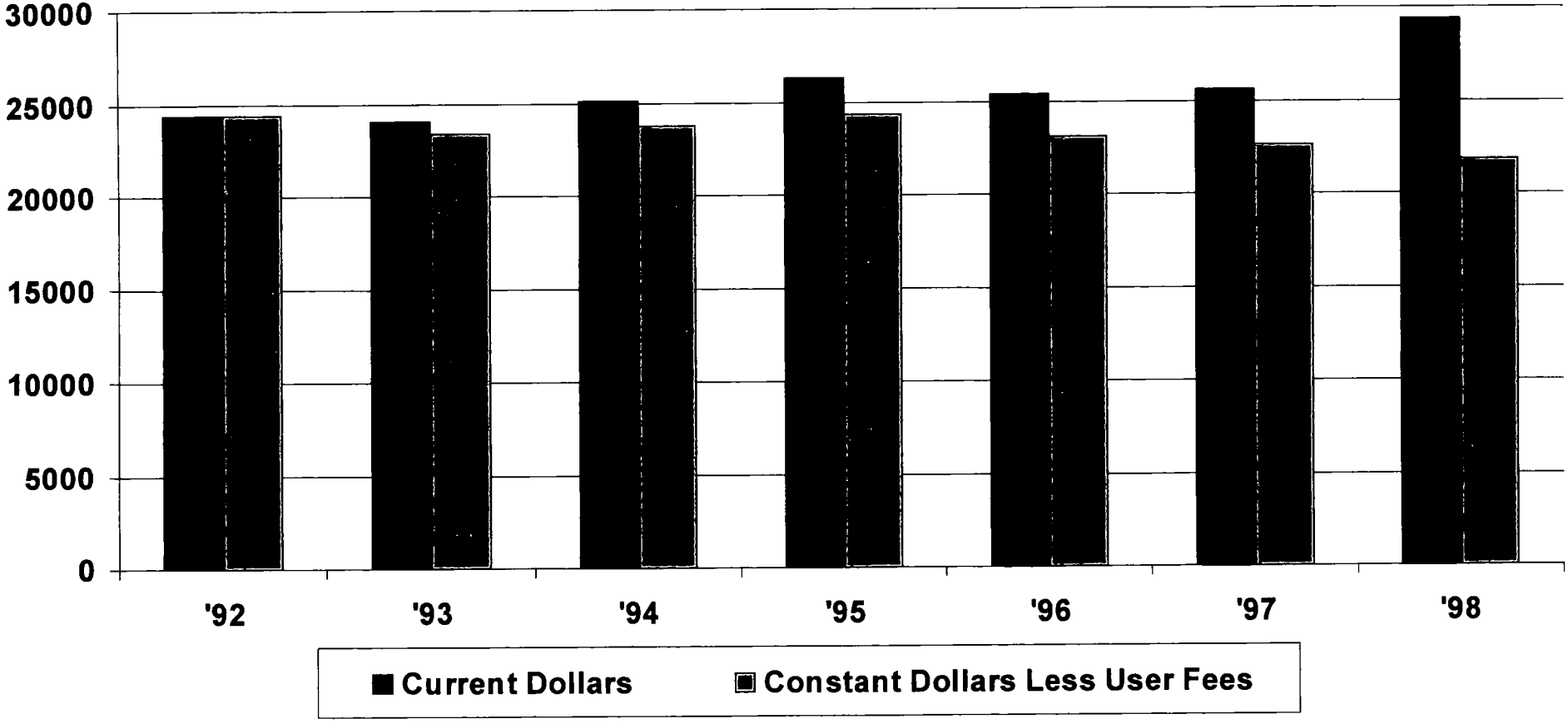
FDA'S BIOLOGIC RESOURCES*
(in millions)



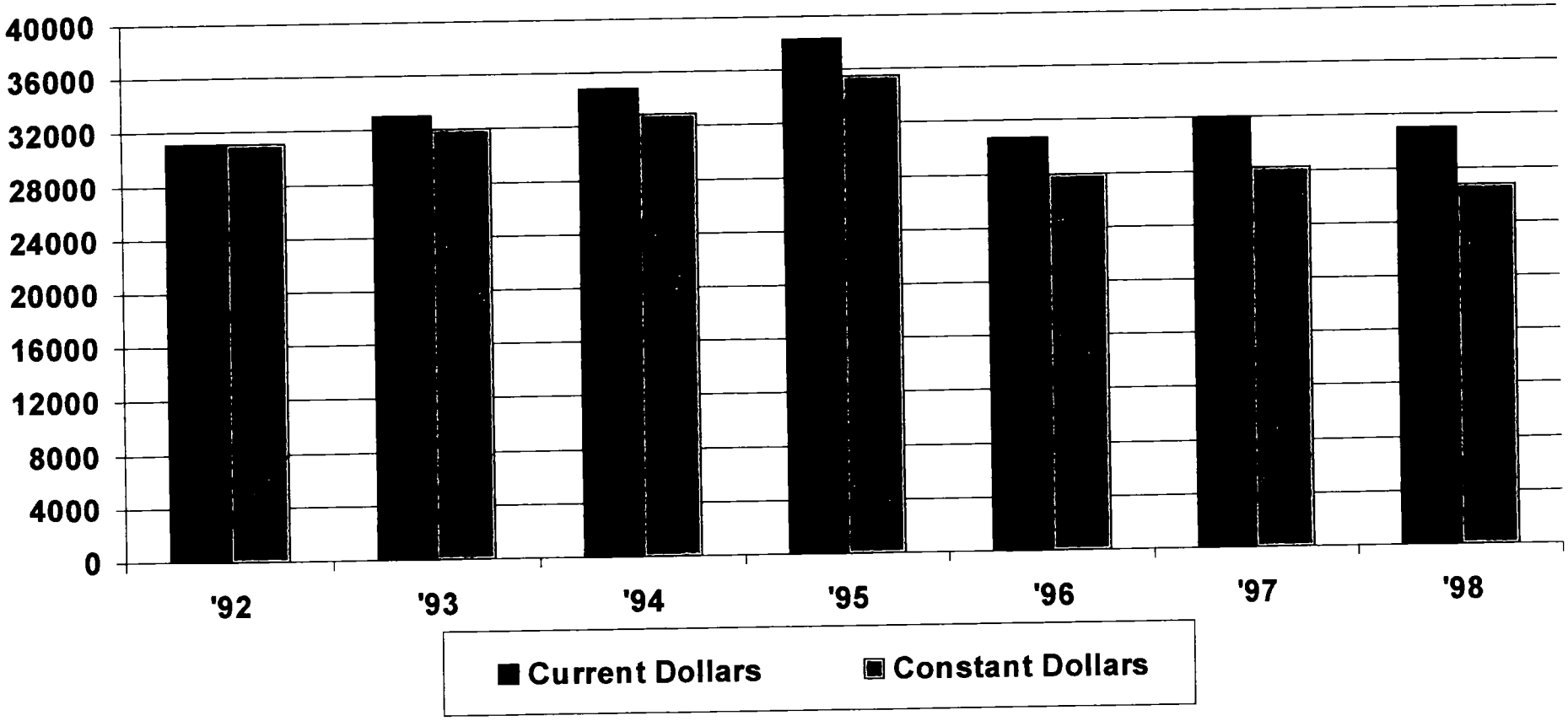
FDA'S MEDICAL DEVICE RESOURCES*



FDA'S VETERINARY MEDICINE RESOURCES*
(in millions)

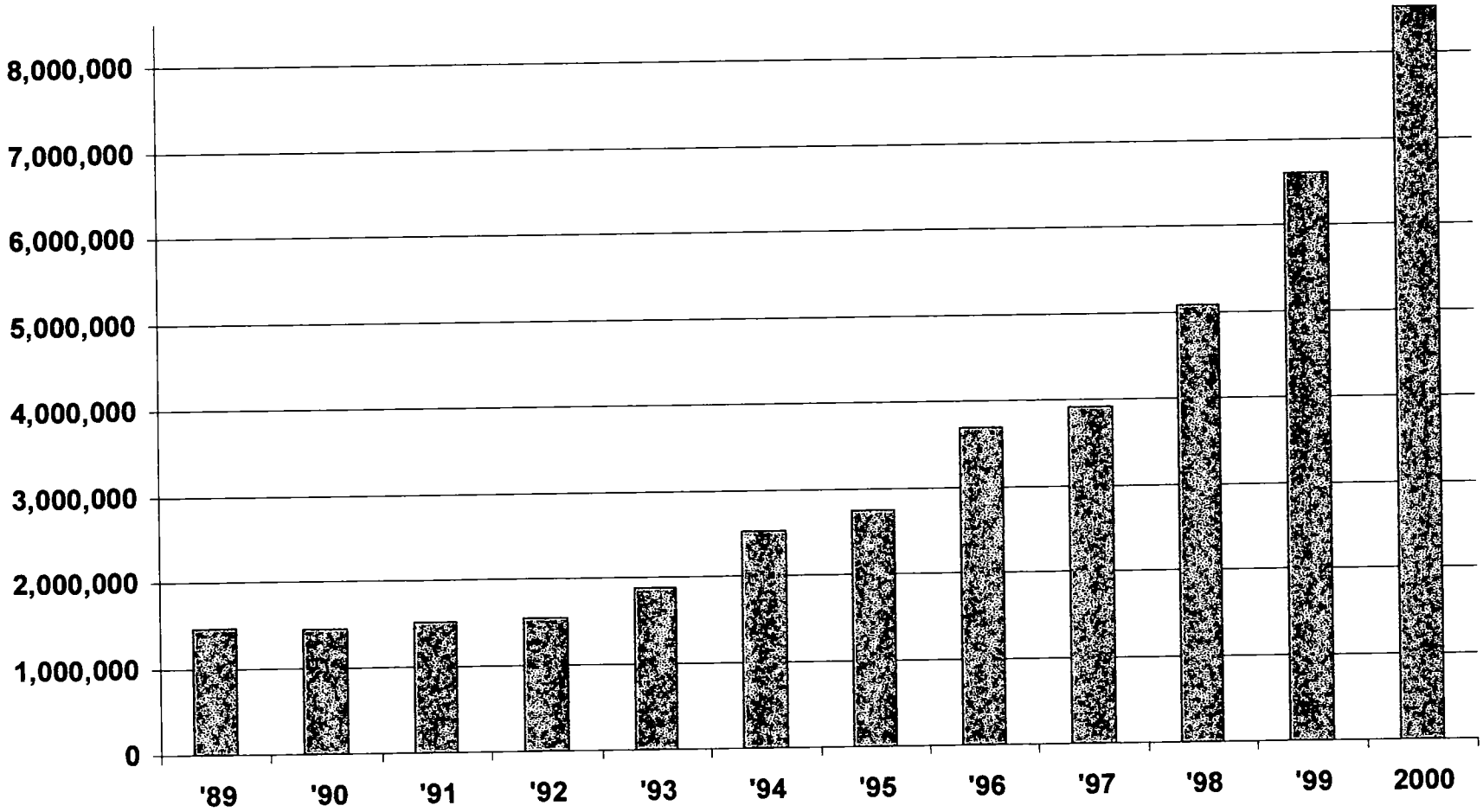


FDA'S TOXICOLOGICAL RESOURCES*



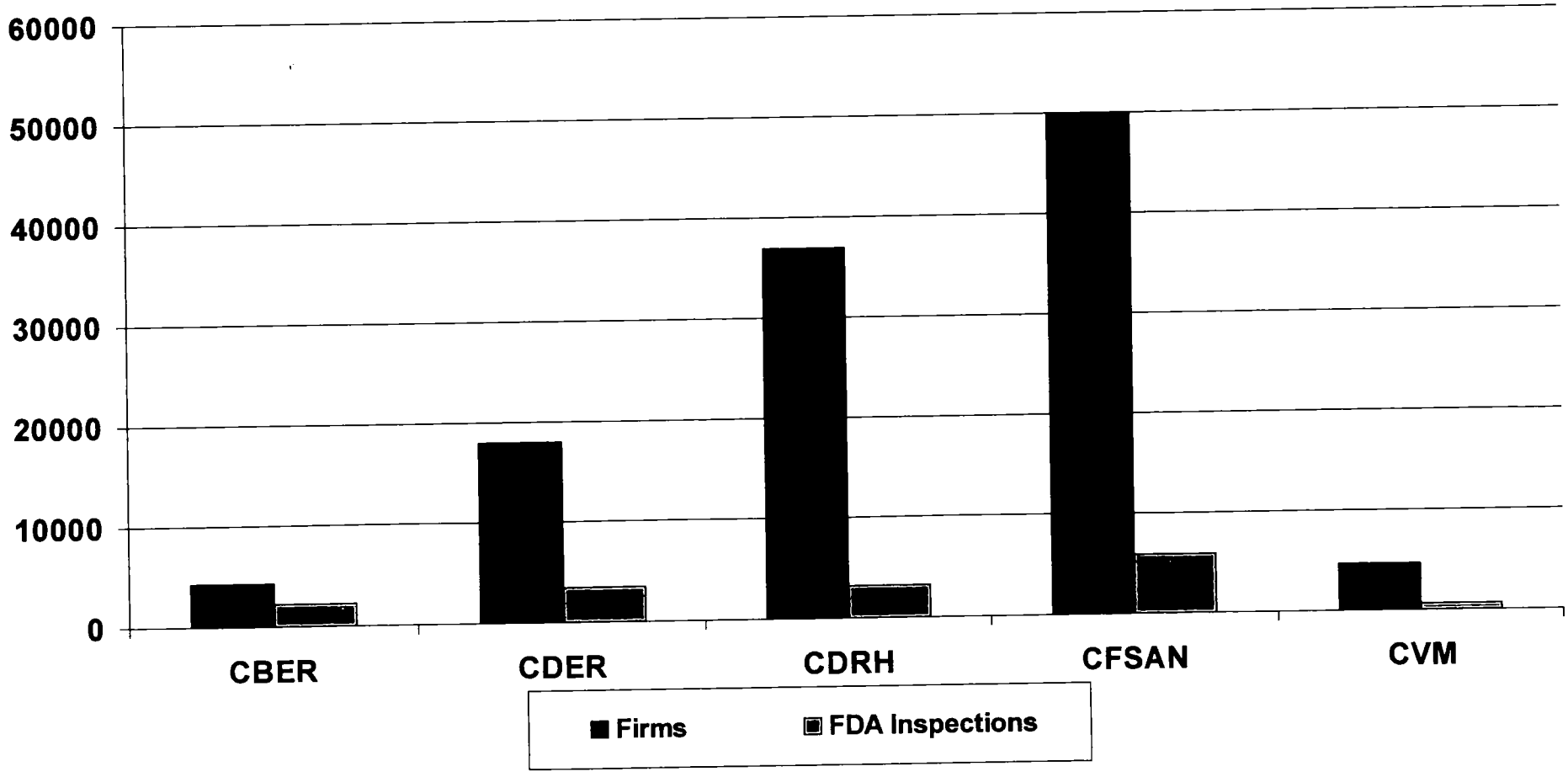
Inspections

FDA IMPORT ENTRIES

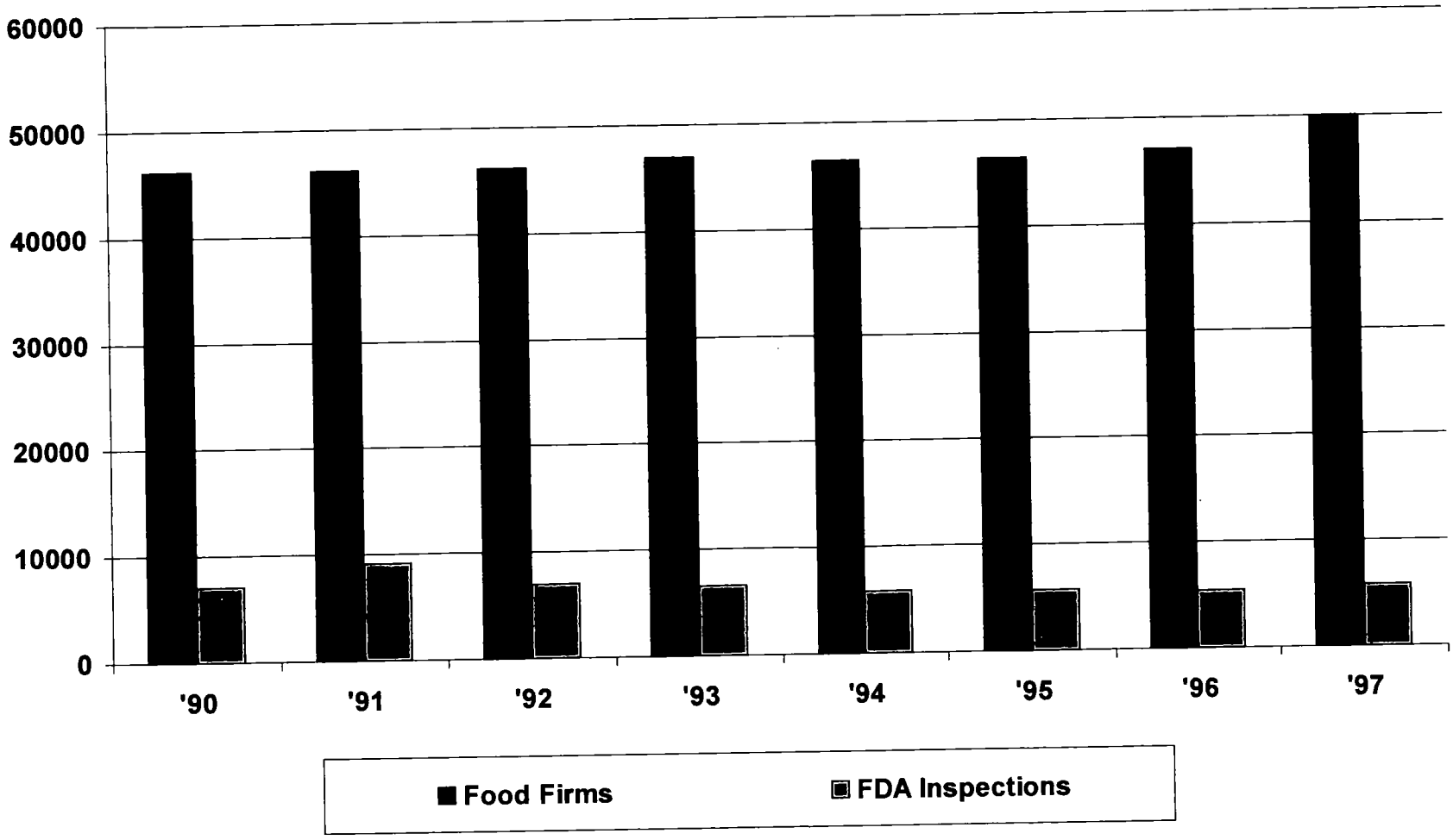


Note: The numbers for the years 1998, 1999 and 2,000 are projected

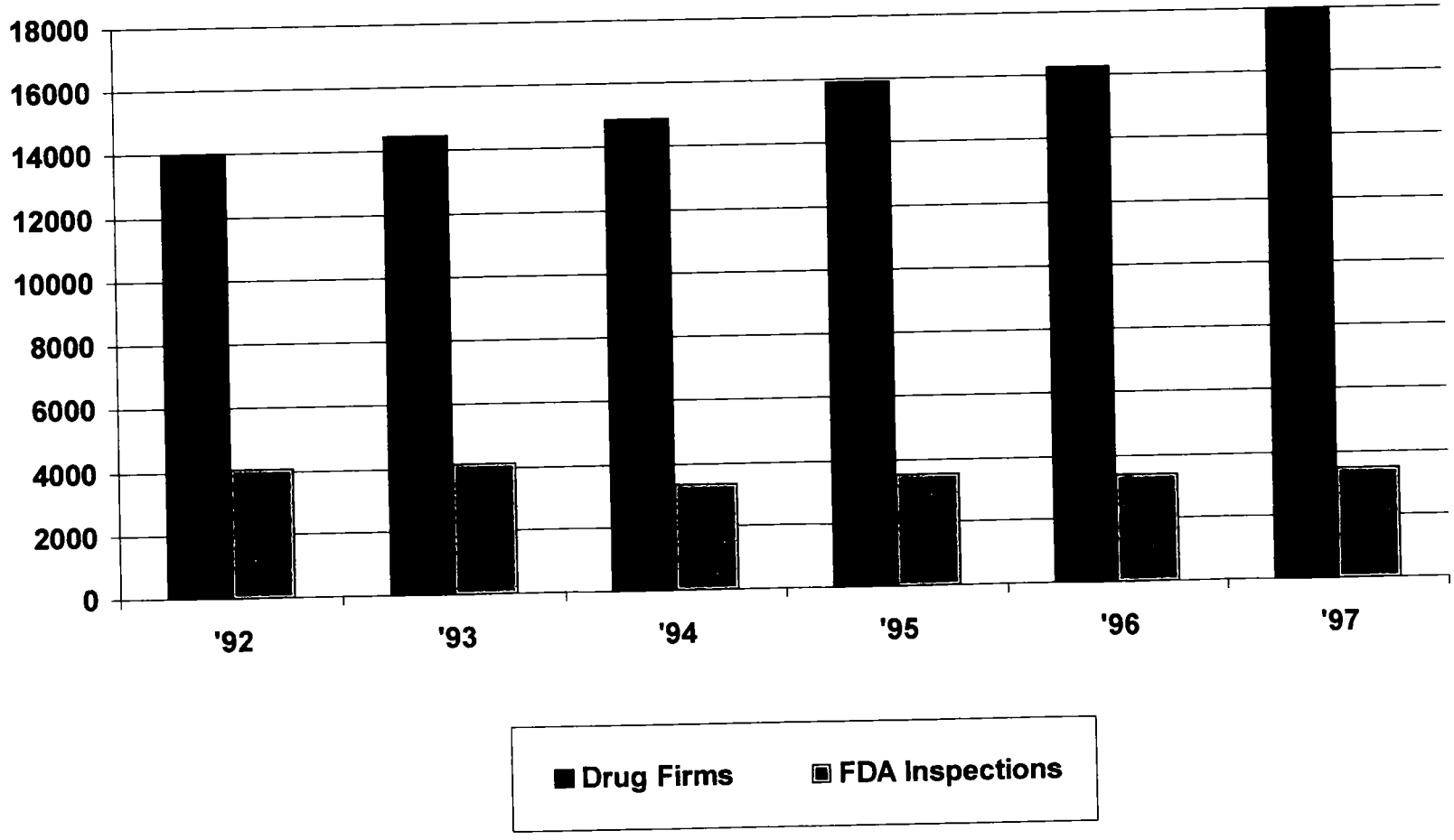
FIRMS TO BE INSPECTED V. ACTUAL INSPECTIONS IN 1997



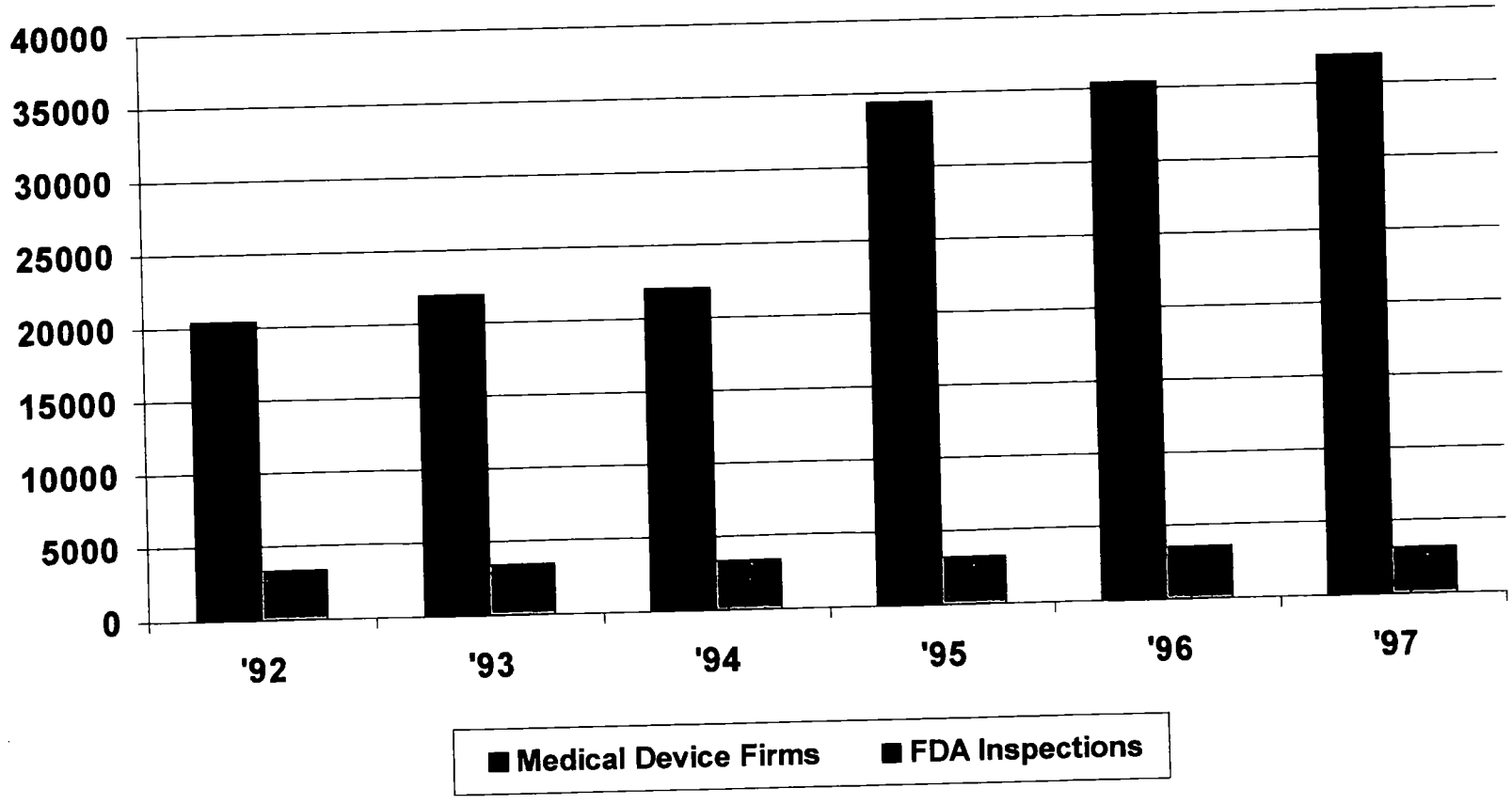
DECLINING FOOD INSPECTIONS



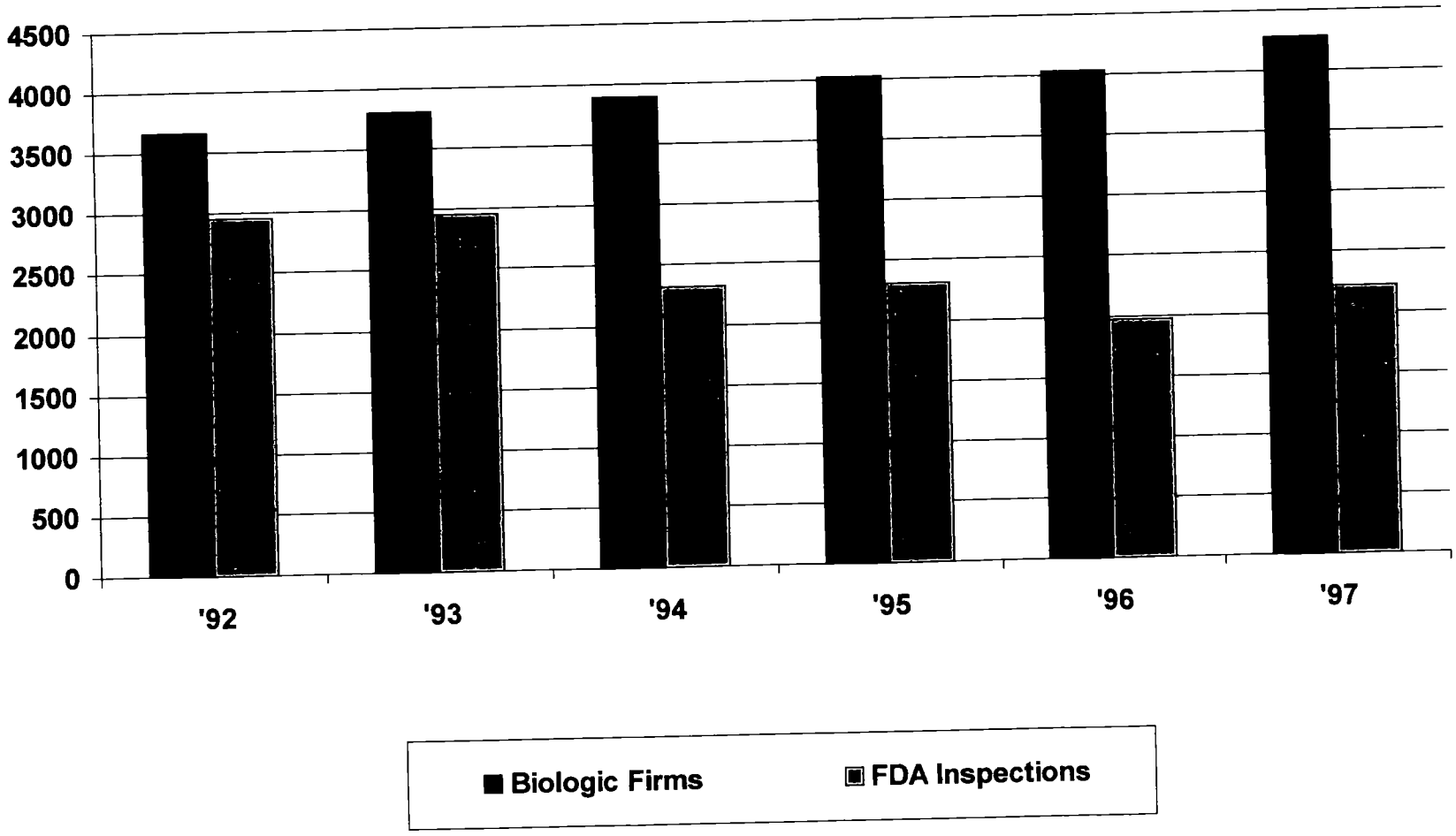
DECLINING DRUG INSPECTIONS



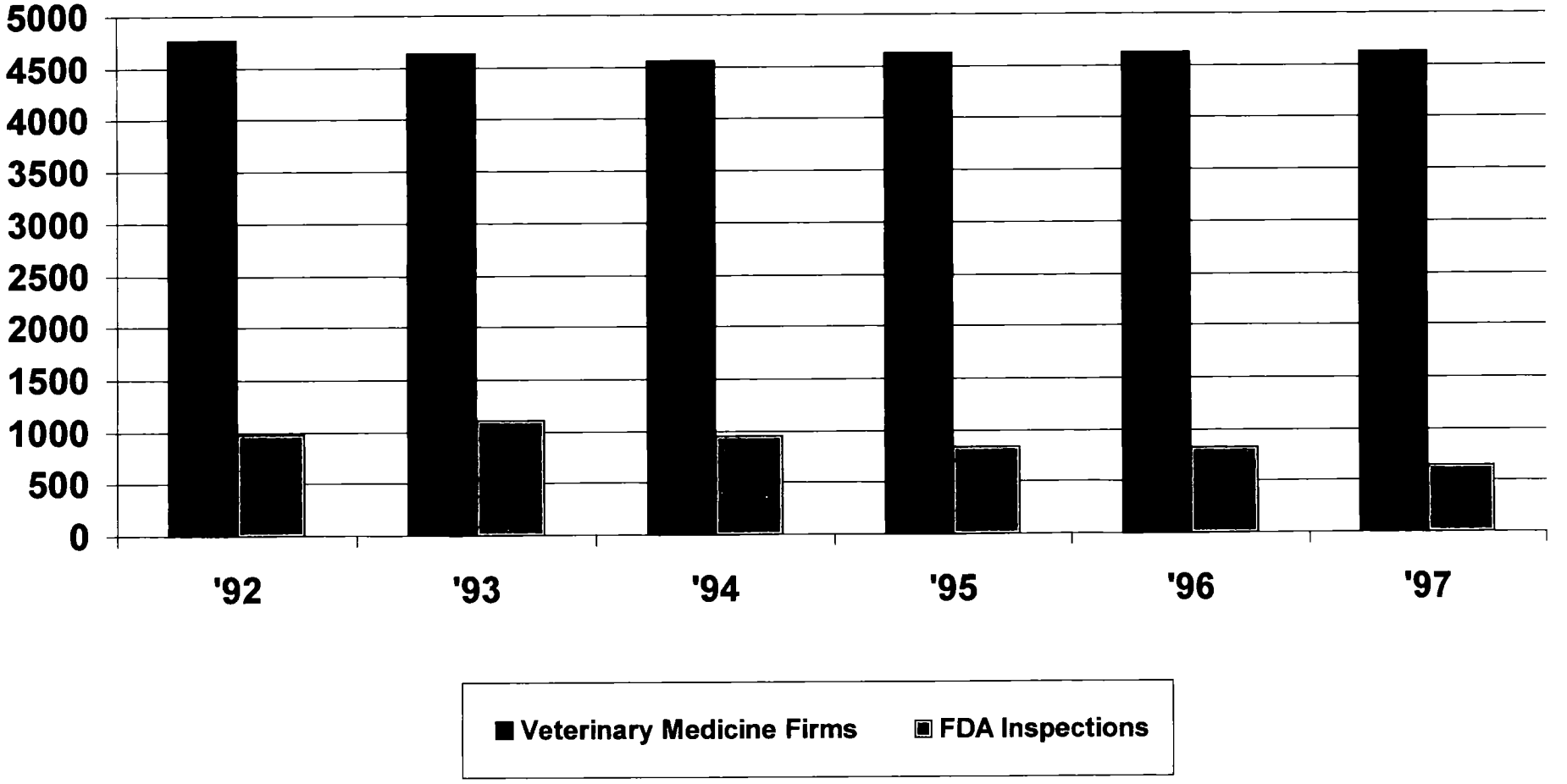
DECLINING MEDICAL DEVICE INSPECTIONS



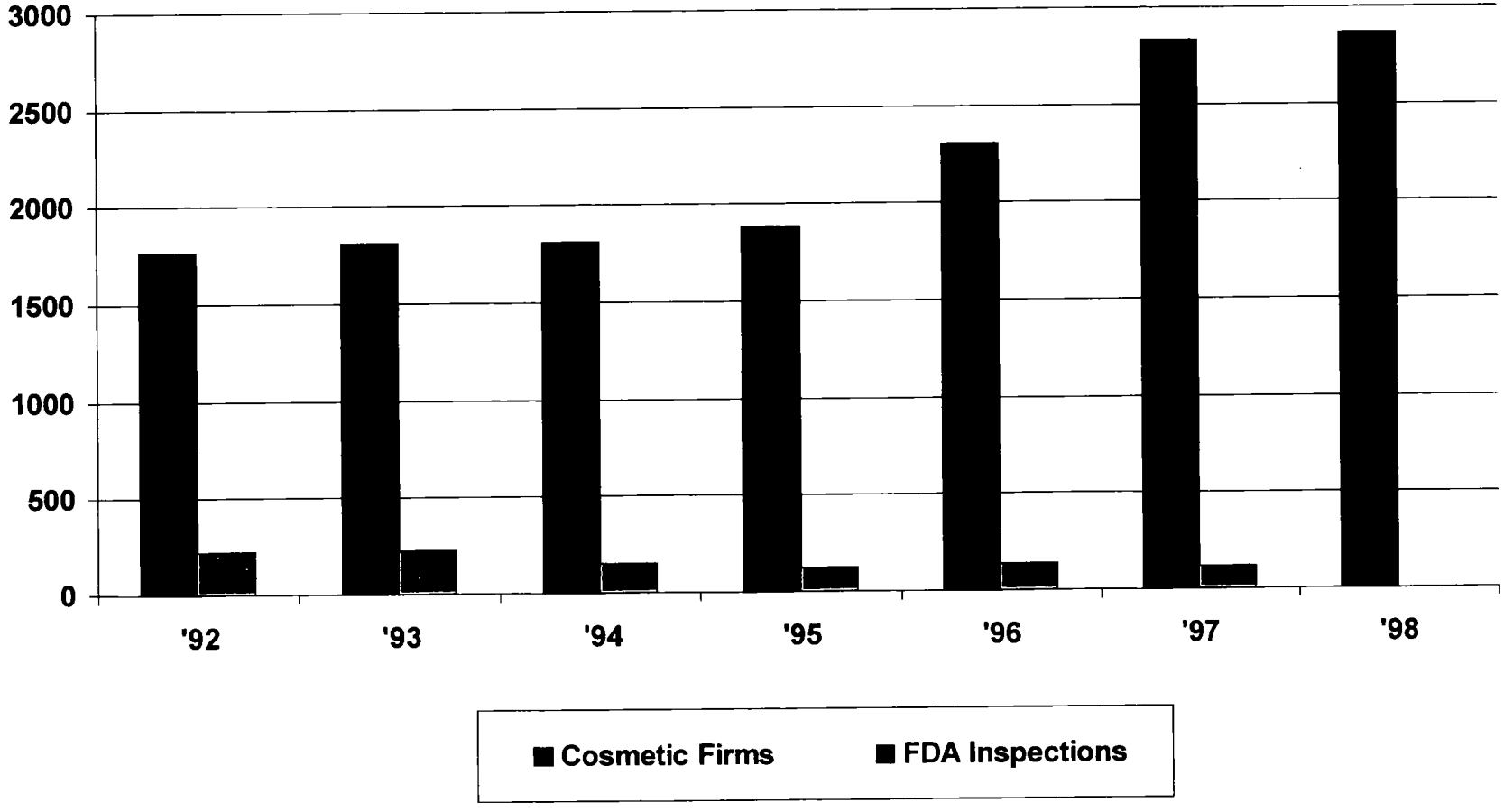
DECLINING BIOLOGIC INSPECTIONS



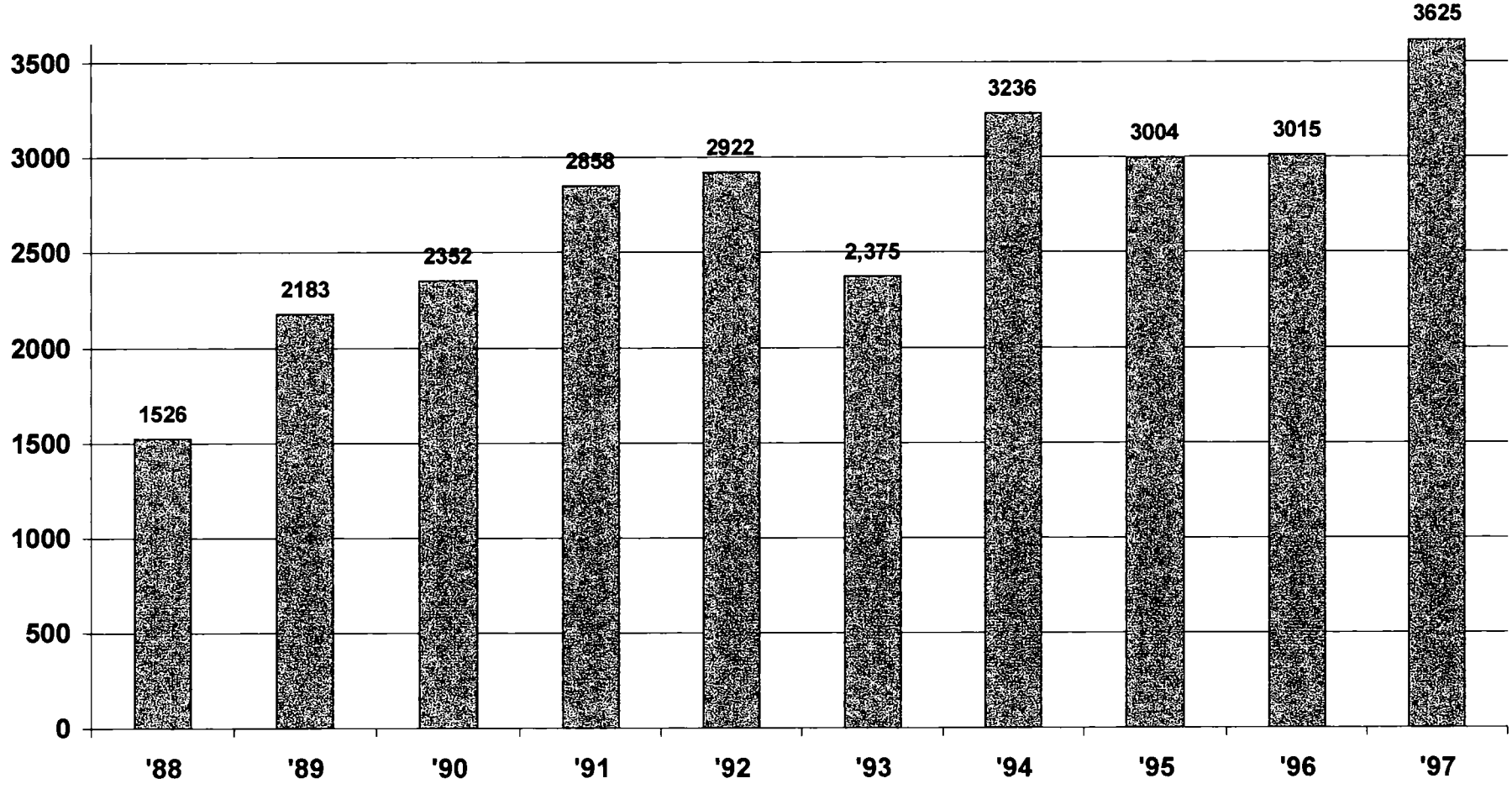
DECLINING VETERINARY MEDICINE INSPECTIONS



DECLINING COSMETIC INSPECTIONS



TOTAL RECALLS



PRODUCTS VIRTUALLY UNREGULATED

(DIETARY SUPPLEMENTS)

VOLUME: Hundreds of products

$12 billion in annual sales; annual increase in sales of 20-30%

HEALTH RISK: Over 3,000 annual injury reports since 1995, 100 deaths

Rate of reporting rapidly increasing

Actual injuries estimated at 30,000-300,000 annually

Products vigorously promoted to children and pregnant women

MINIMAL FDA OVERSIGHT: Less than 10 FTEs

60 inspections per year (of approximately 1,000 firms)

PRODUCTS VIRTUALLY UNREGULATED

(COSMETICS)

VOLUME: Hundreds of products; over 10,000 ingredients; $25 billion industry

HEALTH RISK: Hundreds of annual injury reports; actual injuries estimated to be far higher

Many ingredients suspected of causing cancer, allergic reactions, other effects

200 physician visit for cosmetic-caused illnesses per million products purchased

FDA OVERSIGHT: Less than 10 FTEs, down from over 40 in past

Zero inspections in 1998 (of approximately 1700 firms)

PRODUCTS VIRTUALLY UNREGULATED

(DRUGS PURCHASED OVERSEAS)

VOLUME: Hundreds of products, almost all not approved for U.S. marketing

Hundreds of Internet sites, foreign pharmacies

Sales unknown but increasing rapidly

HEALTH RISK: Unknown but potentially enormous (Drugs are of unknown makeup/safety/effectiveness)

Some products banned in U.S. for safety reasons

FDA OVERSIGHT: Approximately 5 FTEs (to cover over 400 Internet sites, thousands of daily shipments, perhaps millions of annual entries)

PRODUCTS VIRTUALLY UNREGULATED

(PESTICIDE MONITORING)

VOLUME: Over 300 pesticides used on food

Millions of imported food entries into the U.S. each year (1/4 of all fresh fruit and vegetable consumption by Americans)

HEALTH RISK: Unknown but potentially significant without govt. vigilance

FDA OVERSIGHT:

1) Sampling of imports for pesticides has dropped from 11,000 samples in 1989 to 5400 in 1997 (of 2.2 million food importations); domestic sampling has dropped by 50%.

2) FDA has historically gauged the use of both legal and illegal pesticides by foreign producers via a contract to collect information on such usages (thereby enabling the agency to target particular products or countries for careful scrutiny). Funding constraints have forced cancellation of that contract.

3) For domestic usage, FDA historically has performed "field" sampling for pesticides by testing foods sampled from the marketplace. This program is being phased down due to budget constraints, and cannot carry out the needed focus on the diets of infants and young children.

PRODUCTS VIRTUALLY UNREGULATED

(HEALTH/ECONOMIC FRAUD)

VOLUME Ubiquitous problem

Products marketed via internet, in magazines, via direct mail and numerous other sources

HEALTH RISK: Most serious, difficult-to-treat diseases often targetted (AIDS, cancer, Alzheimer's muscular dystrophy, ALS)

Many permutations, e.g.,

- Effective treatment not sought/delayed/stopped in favor of relatively safe but fraudulent therapy
- Safe and effective therapy replaced by dangerous and ineffective product
- Harmless but expensive products that claim to improve general health or appearance (e.g., weight loss, hair growth, fitness)

As FDA's presence has dropped in recent years, more products being seen that cause direct health hazards

[Economic costs unknown, but estimated to be in the billions in wasted consumer income, plus billions more in health care costs (from direct effects or from delays in effective treatment).]

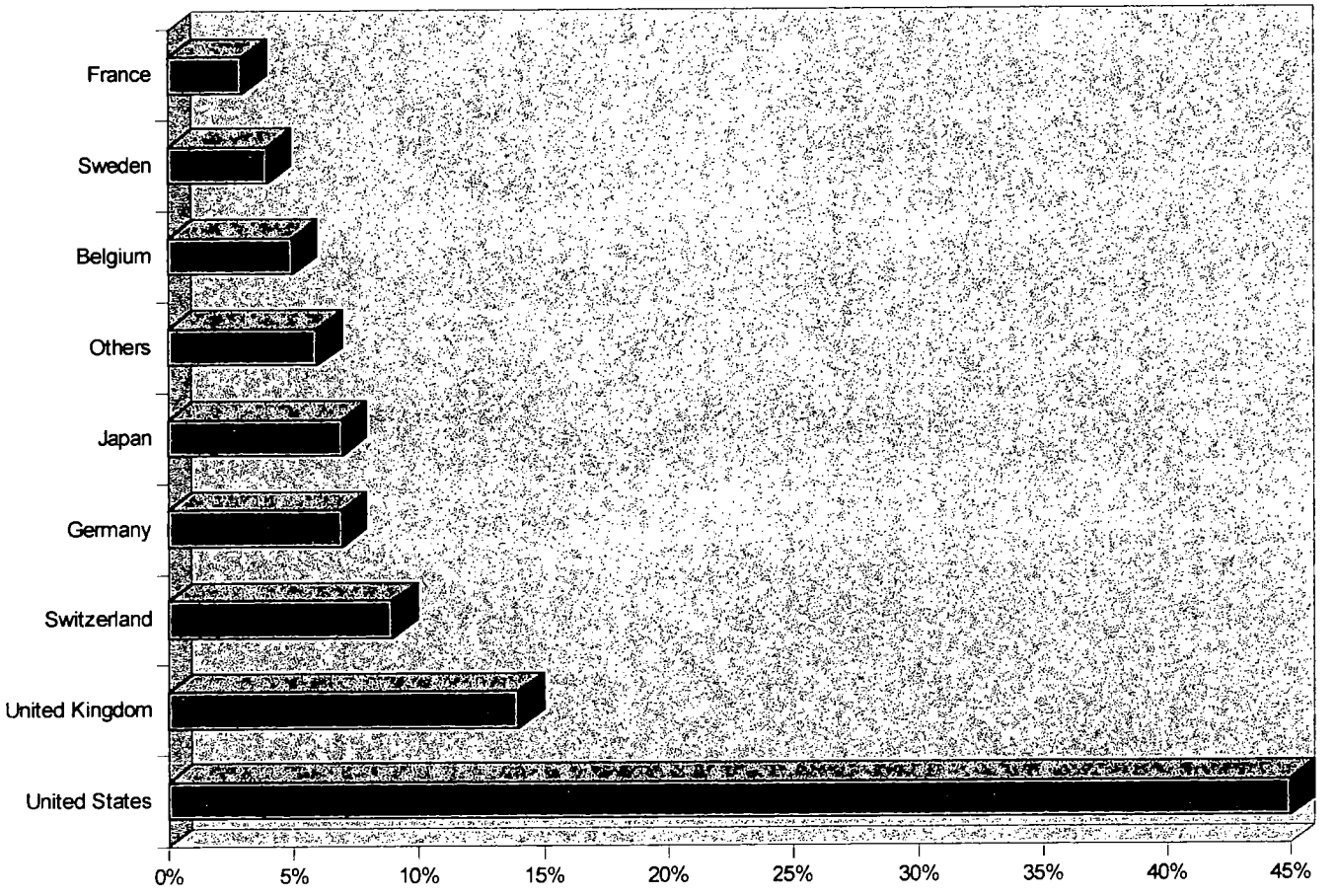
FDA OVERSIGHT: Small program of 10 FTEs cut since 1990 to current 5 FTEs

40 enforcement cases brought in 1997 (of hundreds of fraudulent products)

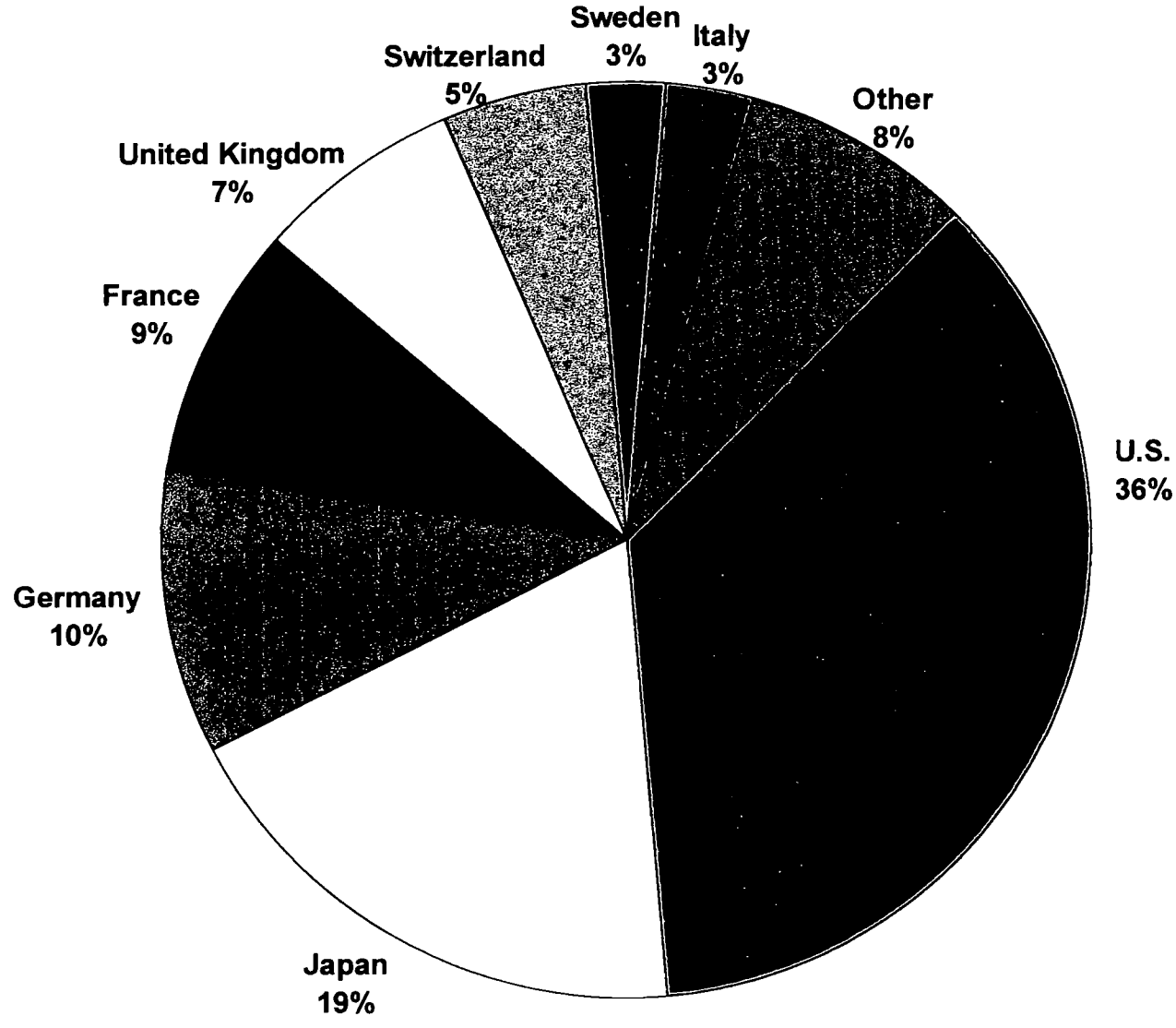
FDA IS CRITICAL TO TECHNOLOGICAL INNOVATION AND COMPETITION

- THE UNITED STATES LEADS THE WORLD IN:
  - -- PHARMACEUTICAL INNOVATION
  - -- RESEARCH AND DEVELOPMENT
  - -- BIOTECHNOLOGY
- REMARKABLE NEW ADVANCES ARE ON THE HORIZON
- BUT, FDA MUST BE PREPARED TO GET THEM ON THE MARKET
- CASE IN POINT: GENERIC DRUGS

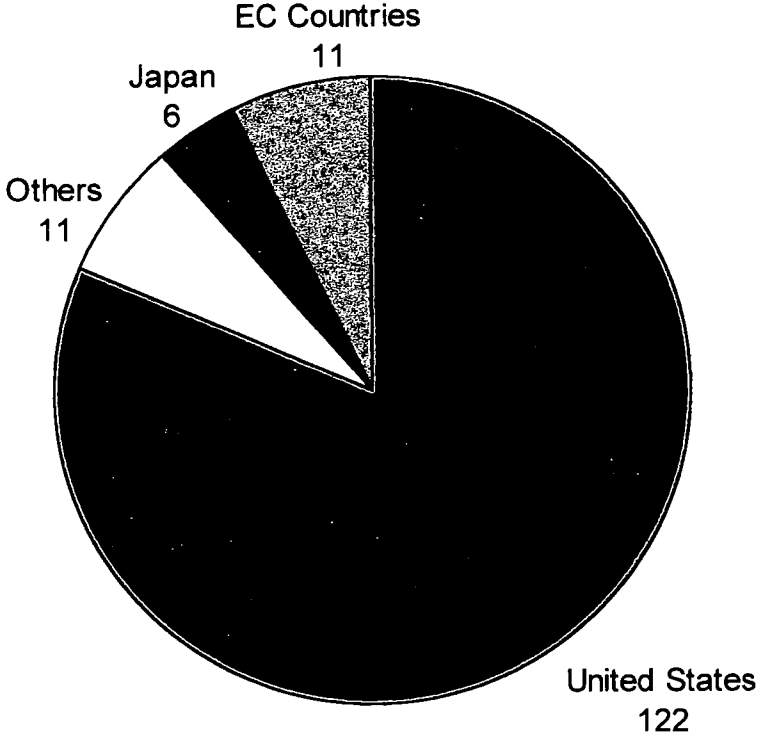
Development of 152 Global Drugs By Country of Origin, 1975-1994



COMPANY-FINANCED PHARMACEUTICAL R&D BY COUNTRY, 1995



U.S. GENETIC ENGINEERING PHARMACEUTICAL/HEALTH CARE 1995 PATENTS (BY COUNTRY OF ORIGIN)



NEW HEALTH CARE AND TECHNOLOGICAL ADVANCEMENTS

-- Gene therapy (cystic fibrosis, cancer)

-- Anti-sense oligonucleotides (cancer, infection, AIDS)

-- Virtual reality for diagnostics (combines CAT with virtual reality)

-- Growth factors (broken bones, ulcers, spinal cord injuries, burns)

-- Use of transgenic animal tissue to produce drugs

-- Foods modified with more functional components

-- Food additives and packaging with antimicrobial properties

-- Robotic surgical assist devices

-- Genetic tests

-- Bioterrorism Products and New Vaccines (DNA vaccines for AIDS, malaria, etc.)

-- Xenotransplantation (animal organs for humans)

A CASE IN POINT: GENERIC DRUGS

Economic benefit:

- "The purchase of generic drugs reduced the cost of prescriptions by roughly $8 billion to $10 billion in 1994."*
- Many of the most important (and expensive) brand name drugs will be coming off patent (and eligible for generic competition) in the next 5 years

Generic Drug Applications:

1994 - 322	1995 - 411
1996 - 453	1997 - 464

Backlog of Pending Applications:

1994 - 457	1995 - 545
1996 - 561	1996 - 581

The Future:

Further delays in approvals due to:

- No staff increases
- No resources to automate
- New forms of drugs using complex delivery systems that cannot easily show therapeutic equivalence

Adverse Events

The Costs of Adverse Drug Events

- > 100,000 deaths/1.3 million serious injuries in hospitalized patients due to ADEs from properly prescribed and administered drugs

- 15.1% of hospitalized patients experience an ADE

  * ADEs are the most frequent type of adverse event in hospitalized patients

- Drug- related illness and death in the U.S. cost ~ $80 billion annually

  * The cost to the U.S. government is ~ $ 26 billion annually

  * ~32% of health care costs are federally funded

- Rapidly escalating number of ADE reports filed with FDA

  * 251,000 ADE reports in 1997 as compared to 50,000 10 years prior

  * increased reporting probably due to: 1) FDA efforts to encourage reporting; 2) increasing number of available drugs secondary to rising number of NDAs and faster approval times; 3) increasing number of drugs for serious diseases for which a higher adverse event risk is tolerated

  * If 80% of ADEs reported, FDA would process ~ 2 million reports/year

  * At most, 10% of ADEs are reported

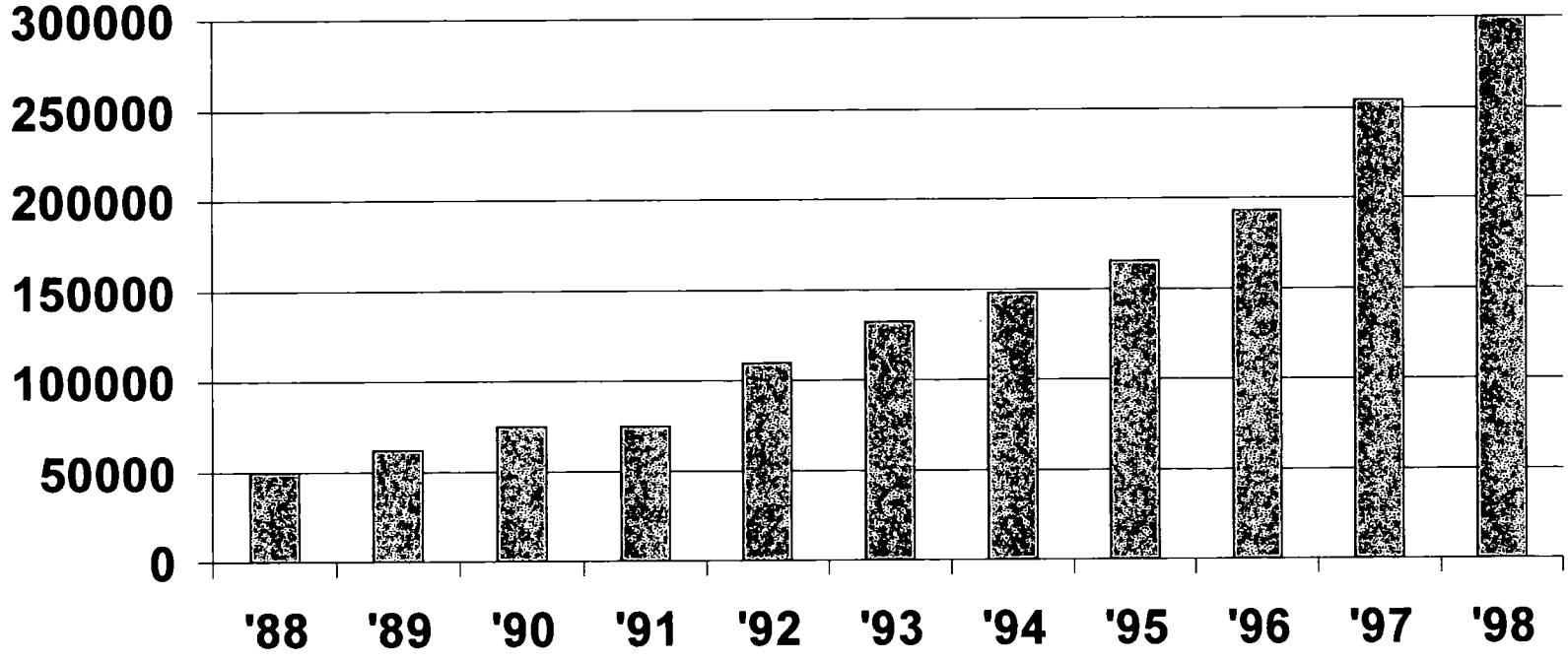
- ADEs may become even more pronounced in the future

  * 75% increase in outpatient visits between 1987 and 1997

  * Practitioners will be less able to monitor and control ADEs

- Current industry standard for monitoring ADEs is 1 reviewer per 1,000 reports; FDA has 1 reviewer per 10,000 reports

ADVERSE DRUG EVENT REPORTS



Note: The figure for 1998 is projected

Citizen Petitions

PENDING PETITIONS
DOCKETS MANAGEMENT BRANCH
DIVISION OF MANAGEMENT SYSTEMS AND POLICY
NOVEMBER 1977 - NOVEMBER 1997 *

Our records indicate that the following petitions have not received final action. If, however, a final or interim response has been sent to a petitioner, and it is not reflected on this report, please forward a copy of the correspondence to the DMB so that we can update our files.

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Anticancer Drugs	COMM	Robert Young	80P-0115 PRC 1	11/12/81	05/11/82	
Anticancer Drugs	COMM	Robert Young	80P-0115 PSA 1	11/19/81	05/18/82	
Toxic Metals and Prevention of Birth Defects and Learning Disabilities	COMM	Nat Network to Prevent Birth Defects	86P-0038/CP 1	01/21/86	07/21/86	052686
Request for Rulemaking to Implement the Orphan Drug Act	COMM	Amgen, Inc.	89P-0443 CP 1	10/16/89	04/16/90	
Minimum Physical Security Needs in all FDA-occupied Buildings	COMM	James G. Dickinson	92P-0005 CP 1	01/07/92	07/06/92	
Essential Use of CFC in Dental Handpiece Solvent, an Aerosol Product	COMM/CBER CVM/CDRH	Midwest	94P-0073 CP 1	01/26/94	07/25/94	
"Smokeless Cigarette" or Smokefree Cigarette" "Eclipse"	COMM	Action on Smoking and Health	94P-0456 CP 1	12/23/94	06/21/95	
Experimental drugs/military personnel w/o informed consent	COMM	Public Citizen Litigation Group et al	96P-0147 CP 1	05/07/96	11/03/96	
Exempt Requirements government the Sale and Distribution of Cigarettes	COMM	Missouri Dept. Of Health	96N-0249 AP 1	12/24/96	06/24/97	
Classify Rongchang Gangtai	COMM	Sinomedical Development	96P-0483 CCP	12/03/96	06/10/97	100697
Establish a guideline on information disseminated on the internet	COMM	Internet Medical	96P-0501 CP 1	12/23/96	06/21/97	
Alternative Establish Names for Smokeless Tobacco Products	COMM	U S Tobacco Co., Conwood Co Et al	97P-0127 CP 1	03/26/97	09/23/97	110697
Amend the Advisory Committee Regulations	COMM	IMDAC	97P-0150 CP 1	04/11/97	10/11/97	102897
"Smokeless Cigarette" or Smokefree Cigarette" "Eclipse"	COMM	R. J. Reynolds Tobacco Co.	94P-0456 CP 3	04/18/97	10/15/97	110697
Advisory Opinion on Admatic Merchandising Machines, Tobacco	COMM	R F Nestler & Associates, Inc.	97A-0241 AP 1	06/13/97	12/14/97	
Revoke confidentiality of INDs, pending & unapproved NDAs et	COMM	Mark Sokolow, Attorney at Law	97P-0295 CP 1	07/10/97	01/07/98	
Amend vending machine regs to add except for locking device	COMM	AMOA, Amusement & Music Operators Assn.	97P-0330 CP 1	08/04/97	01/31/98	

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Regulate cigars, little cigars, as nicotine delivery systems	COMM	Action on Smoking & Health (ASH)	97P-0341 CP 1	08/13/97	02/10/98	
Rescind Approval of the Micro Condomand Female Condom	CDRH	Nat Women's Health Network	88P-0431 CP 1	12/15/88	06/14/89	052390
Reclassification Petition under Section 513(e) for Lipectomy Systems	CDRH	American Society for Anesthetic Plastic Surgery	88P-0439 CP 1	12/23/88	06/22/89	
Virapap Human Papillomavirus DNA Detection Kit	CDRH	Public Citizen/Health Research Group	88M-0446 PRC 1	03/30/89	09/26/89	
Exemption from Preemption on Hearing Aids	CDRH	State of Vermont	89P-0314 CP 1	07/16/89	01/23/90	091890
Reclassify Root & Blade Form Endosseous Dental Implants 513(e)	CDRH	Dental Implant Manufacturers Association	88N-0244 CP 1	12/12/89	06/10/90	
Reclassify Endosseous Dental Implants or Prosthetic Attachment	CDRH	Dental Implant Manufacturers Association	88N-0244 CP 2	06/05/90	12/03/90	12/10/90
Permission to Use Alternate Labeling for UVB Sunlamps	CDRH	New Horizons Enterprises Inc.	90V-0371 VAR 1	10/29/90	04/29/91	
Laser Light Show	CDRH	Melles Griot, Electro-Optics Division	91V-0112 VAR 1	03/20/91	09/16/91	07/12/91
Exemption from Records & Reports Requirements	CDRH	Picker International, Inc.	91V-0210 VAR 1	06/03/91	12/02/91	
Laser Light Show	CDRH	Photon Productions	91V-0341 VAR 1	08/16/91	02/18/92	
Variance for a Class II Laser Product Laser Pointer	CDRH	Laserex Technologies Pty. Ltd	91V-0379 VAR 1	09/23/91	03/23/92	
Recall of Hip & Knee Prosthetic Devices	CDRH	Florence B. Horowitz	91P-0416 CP 1	10/09/91	04/13/92	
Cardiovascular Devices: PMA of the replacement heart valve	CDRH	Chathamborough Research Group Inc.	85N-0331 CP 1	11/19/91	05/18/92	06/12/92
Variance Request for Laser Pointer LP-2000	CDRH	Laserex Technologies Pty Ltd.	91V-0459 VAR 1	11/19/91	05/18/92	
Variance Request for Laser Pointer LP-2000	CDRH	Laserex Technologies Pty Ltd.	91V-0459 VAR 2	11/19/91	05/18/92	
Variance Request for Laser Pointer LP-2000	CDRH	Laserex Technologies Pty Ltd.	91V-0459 VAR 3	11/19/91	05/18/92	
Proxima Laser Pointer A90 Beam Attenuator	CDRH	Laserex Technologies Pty Ltd.	92V-0002 VAR 1	01/02/92	07/01/92	
Variance for a Laser Pointer	CDRH	Diode Laser Concepts, Inc.	92V-0010 VAR 1	01/13/92	07/13/92	
Variance for Beam Attenuator	CDRH	Laserex Technologies Pty Ltd.	92V-0044 VAR 1	01/24/92	07/22/92	
Variance request for the LDP-350AV beam attenuator	CDRH	Laserex Technologies Pty Ltd.	92V-0119 VAR 1	03/03/92	09/08/92	
Variance request for the LDP-450AV beam attenuator	CDRH	Laserex Technologies Pty Ltd.	92V-0120 VAR 1	03/03/92	09/08/92	
Variance request for radiographic system	CDRH	St. Joseph's Hospital	92V-0128 VAR 1	03/05/92	09/08/92	
Variance request for laser pen pointer PP10	CDRH	Imatronic Ltd.	92V-0006 VAR 2	03/24/92	09/21/92	
Exemption for the SM-815/AVR-2 laser simulator	CDRH	Hughes Danbury Optical Systems, Inc.	92V-0168 VAR 1	04/06/92	10/05/92	

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Declassify external assembled lower limb prosthesis	CDRH	American Orthotic and Prosthetic Assn.	92P-0173 CP 1	04/13/92	10/13/92	
Model 4 laser projector	CDRH	Astronaut Memorial Space Science Center	92V-0178 VAR 1	04/14/92	10/13/92	
Reconsider and permit restricted distribution of the MY-PAP	CDRH	Medtech Diagnostics Inc.	92P-0204 PRC 1	05/05/92	11/02/92	
Variance for Automatic Collimation Devices	CDRH	Johnston Memorial Hospital	92V-0248 VAR 1	06/02/92	12/07/92	
Laser Light Show	CDRH	University of Nebraska at Omaha	92V-0310 VAR 1	07/29/92	01/25/93	
Immediately extend the current embargo of the Siemens-Elema AB Patient Care Systems Servo Ventilator, Model 900C	CDRH	Public Citizen/Health Research Group	92P-0326 CP 1	08/13/92	02/09/83	10/07/92
COBRA Laser Pointer Control Switch	CDRH	ALPEC Team, Inc.	92V-0329 VAR 1	08/17/92	02/16/93	
Laser Light Show	CDRH	Technological Artisans	92V-0362 VAR 1	09/14/92	03/15/93	
Variance for Lexel Corolation Model 88	CDRH	Northern Lights	92V-0386 VAR 1	10/06/92	04/09/93	02/08/93
Variance Request for Small Visible Diode Pointer	CDRH	Melles Griot Gas Laser Products	92V-0404 VAR 1	10/20/92	04/19/93	
Laser Light Show	CDRH	Universal Studies Florida	92V-0407 VAR 1	10/27/92	04/26/93	
Variance for emission indicator & beam attenuator	CDRH	Beta Electronics, Inc.	92V-0488 VAR 1	12/09/92	06/07/93	
LMS-1000 Internal Pistol Sight Kit	CDRH	Lasermax, Inc.	92V-0496 VAR 1	12/16/92	06/14/93	
Variance for Beam Attenuator SL007	CDRH	Laserex Technologies	92V-0503 VAR 1	12/22/92	06/21/93	
Variance for Quarton Beamshot Model No. 2000B/2000S	CDRH	Quarton, Inc.	92V-0512 VAR 1	12/30/92	06/28/93	03/10/93
Variance for Beam Attenuator, LDP-500	CDRH	Laserex Technologies Pty., Ltd.	93V-0014 VAR 1	01/11/93	07/12/93	
Variance for Model B-300C Laser Pointer	CDRH	Beta Electronics, Inc.	93V-0051 VAR 1	02/03/93	08/02/93	
Laser Light Show	CDRH	The Aztec Club	93V-0054 VAR 1	02/04/93	08/09/93	
Laser Light Show	CDRH	Drush's Night Club	93V-0071 VAR 1	02/18/93	08/17/93	
Variance for Cipher Device	CDRH	Hewlett-Packard Ltd.	93V-0080 VAR 1	02/23/93	08/23/93	
Laser Light Show	CDRH	MWK Industries	93V-0108 VAR 1	03/12/93	09/08/93	
Variance for Emission Indicator for Hand-held Laser Pointer	CDRH	Peiris Associates	93V-0123 VAR 1	03/22/93	09/20/93	
Variance for Infinity Laser Pointer & Laser Shot	CDRH	ALPEC Team Inc.	93V-0142 VAR 1	04/05/93	10/04/93	
Variance for Laser Shot 2 Emission Indicator	CDRH	ALPEC Team Inc.	93V-0159 VAR 1	04/22/93	10/25/93	
Laser Emission Indicator Class IIIa Laser Pointer 4.5mv	CDRH	Lanel, Inc.	93V-0188 VAR 1	05/21/93	11/22/93	
Variance for Laser pointer, Lite writer	CDRH	ALPEC Team, Inc.	93V-0192 VAR 1	05/26/93	11/22/93	
Extend Exemption for 23 low risk Generic type Dental Devices	CDRH	Dental Manufacturers of America, Inc.	93P-0193 CP 1	06/01/93	11/29/93	

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SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Variance request for laser pointer, model OPON-670-PEN	CDRH	Quarton, Inc.	93V-0206 VAR 1	06/14/93	12/13/93	
Variance for Microlight 930 102VT Beam Attenuator	CDRH	Lasermedics Inc.	93V-0255 VAR 1	07/12/93	01/10/94	
Laser Light Show	CDRH	MWK Industries AG/Laser Projection	93V-0256 VAR 1	07/12/93	01/10/94	
Variance for emission indicator HL-202 Laser Pointer	CDRH	OP. Electronics Co., Ltd.	93V-0261 VAR 1	07/13/93	01/10/94	
PMA of Nonroller-Type Cardiopulmonary Bypass Blood Pump	CDRH	Health Industry Manufacturers Association	93M-0150 CCP 1	07/21/93	02/22/94	04/20/94
Laser Light Show	CDRH	Laserworks	93V-0278 VAR 1	07/28/93	02/24/94	
Laser Light Show	CDRH	Radon Testers of America DBA PJ's Projection TV Sales and Rentals	93V-0279 VAR 1	07/29/93	01/25/94	
Exemption from Preemption on Hearing Aids	CDRH	International Hearing Society (IHS	89P-0314 CP 2	09/01/93	02/28/94	
Change in Classification for Ostomy Pouch & Accessories	CDRH	Abraham L. Lastnik	93P-0355 CCP 1	09/15/93	04/14/94	08/07/95
Laser Light Show	CDRH	Lasertronics	93V-0343 VAR 1	09/21/93	03/21/94	
Exemption Dardik Biograft Human Umbilical Vein Graft	CDRH	Bio-Vascular Inc.	93P-0410 CP 1	10/28/93	12/27/93	
Ban and Reclassfy Dental Mercury	CDRH	I. Cheraskin, MD, DDS & M. Ringsdorf, DMD	93P-0424 CP 1	11/02/93	05/02/94	06/16/94
Variance for Vascular Graft Prostheses	CDRH	Intervascular, Inc.	93V-0426 VAR 1	11/02/93	02/02/94	
Variance for Hand Held Laser Illuminator	CDRH	McDonnell Douglas Corporation	93V-0456 VAR 1	11/26/93	05/22/94	
Amend & Revoke Regulations on Acupuncture Needles	CDRH	William Nelson	93P-0463 CP 1	12/03/93	06/01/94	
Human Umbilical Vein Graft; Exemption from Device Tracking	CDRH	Bio-Vascular, Inc.	93P-0476 CP 1	12/15/93	03/15/94	
Exemption for Left Ventricular Support System BVS 5000	CDRH	Abiomed, Inc.	93P-0477 CP 1	12/15/93	03/15/94	
Tracking Regulations for Infusion Pumps	CDRH	IV Support Systems, Inc.	93P-0488 CP 1	12/22/93	03/22/94	
Essential use/add Vapor-Pressure Powered Implantable Infusion Pump	CDRH	Infusaid Inc.	94P-0001 CP 1	01/04/94	07/05/94	
Laser Light Show	CDRH	Current Trends in Electronics Inc	94V-0024 VAR 1	02/01/94	08/01/94	
Variance Request from Medical Device Tracking Regulations	CDRH	IMPRA, Inc.	94V-0072 VAR 1	03/08/94	06/06/94	07/07/95
Exemption of Device Tracking, Total TMJ Replacement	CDRH	Poly-Medics	94P-0183 CP 1	05/12/94	08/10/94	

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SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Exemption Essential Use Vapor-pressure powered Pumps	CDRH	Therex Corporation	94P-0201 CP 1	05/23/94	08/22/94	
Laser Light Show	CDRH	Cerritos Towne Center	94V-0266 VAR 1	07/11/94	01/10/95	
Essential Use Exemption for Implantable Infusion Pump	CDRH	MiniMed Technologies	94P-0268 CP 1	07/15/94	01/11/95	
Advisory Opinion re: Ophthalmic, Therapeutic Contact Lenses	CDRH	Ocular Instruments, Inc.	94A-0321 AP 1	09/01/94	02/28/95	
Reclassification of Nonabsorbable ePTFE Surgical Suture	CDRH	W.L. Gore & Associates, Inc.	94P-0347 CCP 1	09/20/94	03/20/95	
Certify Mercury/Silver (amalgam)-Classify & Issue Warning	CDRH	Reeves & Graddy (Agent for Petitioners)	94P-0354 CP 1	09/23/94	03/27/95	
AP Re: Preemp State Common Law Tort Claims under Med. Dev. Act	CDRH	Gagilardi & Associates	94A-0399 AP 1	11/02/94	05/01/95	
Laser Light Show	CDRH	Rocket Science Props &Magic Inc.	94V-0406 VAR 1	11/09/94	05/08/95	
Laser Light Show	CDRH	Club Tribeca	94V-0410 VAR 1	11/09/94	05/08/95	
Laser Light Show	CDRH	SciWorks-Science Center & Environetal Park	94V-0436 VAR 1	12/05/94	06/05/95	
Reclassification Petition for Shoulder Joint Metal	CDRH	Orthopedic Surgical Manufacturers Assn.	94P-0445 CCP 1	12/13/94	06/12/95	
Laser Light Show	CDRH	Eclipse Technologies Inc. For Act III	95V-0006 VAR 1	01/11/95	07/10/95	
Importation of Silicone Gel-Filled Breast Prostheses	CDRH	Julian C. Green	95A-0074 AP 1	03/16/95	09/12/95	
Objections Re: Enforcement of Medical Device Regulations	CDRH	Health Industry Manufacturers Association	95P-0077 CP 1	03/17/95	09/13/95	
Laser Light Show	CDRH	Legends In Concert	95V-0083 VAR 1	03/24/95	09/25/95	
Exempt Medical Gases from 21 CFR Part 205	CDRH	Lincare, Inc.	95P-0107 CP 1	04/26/95	10/24/95	
Laser Light Show	CDRH	Sycuan Gaming Center	95V-0118 VAR 1	05/10/95	11/06/95	
Diagnostic Ultrasound Devices - Criteria for 510(k) and PMA	CDRH/COMM	Acuson Corporation	95P-0140 CP 1	05/24/95	11/20/95	
Variance Request for Mobile Fluoroscopic X-Ray System	CDRH	Panoramic Corporation	95V-0144 VAR 1	05/25/95	11/21/95	
Enforce SMDA & Existing Regulations Regarding Manufacturers of dental lubricants	CDRH	Steri-Lube, Inc.	95P-0152 CP 1	06/05/95	12/04/95	
Laser Light Show	CDRH	Towards 2000	95V-0198 VAR 1	07/05/95	01/02/96	
Femidom Female Condom, PMA	CDRH	Family Health International	95M-0119 PRC 1	07/10/95	01/07/96	
Femidom Female Condom, PMA	CDRH	Wisconsin Pharmacal Co.	95M-0119 PRC 2	07/10/95	01/07/96	

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SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Labeling fro Mammogrpahy Bucky & Compression Paddles	CDRH	Technowipe Inc.	95P-0214 CP 1	07/13/95	01/10/96	
Effective Date for PMA's OTC Denture Cushions, Pads, Repair Kits	CDRH	Brimms, Inc.	95N-0034 CCP 1	07/25/95	02/21/96	
Effective Date for PMA's OTC Denture Cushions, Pads, Repair Kits	CDRH	The Mentholatum Company.	95N-0034 CCP 2	07/26/95	02/21/96	
Variance Laser Ace Weapon Sight for Police, Security Agent	CDRH	Lasertrace, Inc.	95V-0236 VAR 1	07/26/95	01/22/96	
Performance Standards for Light-Emitting Products	CDRH	Photonics Specialist	95V-0244 VAR 1	08/02/95	01/30/96	
Laser Light Show	CDRH	Hawaii Laser Light Productions, Inc.	95V-0252 VAR 1	08/04/95	02/01/96	
Classification of Breathing Frequency Monitor	CDRH	HIMA	83N-0193 CP 1	08/22/95	02/18/96	
"Reference List" Procedures Bring into Conformity with Req.	CDRH/COMM	HIMA	94P-0389 CP 2	09/12/95	03/12/96	
Reclassify Automated Differential Cell Counting Devices	CDRH	Abbott Diagnostics	95P-0315 CCP 1	09/22/95	04/19/96	
Request to Reclassify Obstetric Data Analyzer	CDRH	McKenna & Cuneo	95P-0320 CCP 1	09/22/95	04/23/96	
PMA; Femidom Female Condom	CDRH	Wisconsin Pharmacal,Co.	95M-0119 PSA 1	11/02/95	04/29/96	
Laser Light Show	CDRH	In-Neon	95V-0401 VAR 1	12/11/95	06/08/96	
Laser Light Show	CDRH	Lidatek, LLC	95V-0412 VAR 1	12/19/95	06/18/96	
Laser Light Show	CDRH	Telemetry	96V-0004 VAR 1	01/03/96	07/02/96	
Advisory Opinion Regarding Device Model 7424 Itrel II	CDRH	John Melander	96A-0006 AP 1	01/11/96	07/09/96	
Laser Light Show-Jim Stafford Laser Show	CDRH	Jim Stafford Theater	96V-0042 VAR 1	02/12/96	08/10/96	
Variance for an Orthopedic C-Arm Fluoroscopic System	CDRH	Lunar Corporation	96V-0068 VAR 1	02/26/96	08/26/96	
Reclassify polyclonal & monoclonal for lineage assessment	CDRH	Joint Council of Immunohistochemical	96P-0072 CCP 1	03/01/96	09/27/96	10/04/96
Variance for Laser Light Show	CDRH	Quantum Image Multimedia Productions	96V-0077 VAR 1	03/04/96	09/01/96	
Medical Devices Amendments Preempt State Law	CDRH	J. Garrett Kendrick (Law Office of)	96A-0141 AP 1	05/03/96	10/30/96	
Omichrome Med# 532-100MW Image Lasers	CDRH	Image Lasers	96V-0142 VAR 1	05/03/96	11/02/96	
Mobolazer ML10-250, ML10-300, ML10-300C, ML10-1000	CDRH	Marketing Insights Inc	96V-0156 VAR 1	05/15/96	11/13/96	
Variance for OxyMet Model 9910 Beam Attenuator	CDRH	Nonin Medical Inc.	96V-0167 VAR 1	05/24/96	11/25/96	

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SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Laser Light Show	CDRH	Laser Alliance Corporation	96V-0178 VAR 1	05/31/96	11/27/96	
Variance Application re: Laser Certification & Standards for	CDRH	DioLase Corporation	96V-0198 VAR 1	06/14/96	12/15/96	
Variance for BBTSII Heavy-Duty Bed w/Radiolucent Panel	CDRH	Hill-Rom Co	96V-0224 VAR 1	06/28/96	12/26/96	
Reclass.Temporary Mandibular Condyle Implants from Class III	CDRH	Howmedica Leibinger, Inc.	96P-0253 CCP 1	07/16/96	02/11/97	
Laser Light Show	CDRH	Belz Inc.	96V-0246 VAR 1	07/09/96	01/05/97	
Laser Light Show	CDRH	Windy City Music	96V-0252 VAR 1	07/16/96	01/12/97	
Reclassify from class III to class II monitoring device	CDRH	Zymed Medical Instrumentation	96P-0276 CCP 1	07/30/96	10/06/96	
Laser Light Show	CDRH	Mobolazer/Memphis	96V-0281 VAR 1	08/07/96	02/08/97	
Variance for the SIMVIEW 3000 CT therapy simulator	CDRH	Siemens Medical Systems, Inc.	96V-0282 VAR 1	08/07/96	02/24/97	
Variance for Spectra Physics Lasers	CDRH	Trees of Mystery	96V-0295 VAR 1	08/14/96	02/15/97	
Variance for Mobolaser ML10-200, ML10-300, ML10-300W, ML10-1	CDRH	Pegasus Inc.	96V-0296 VAR 1	08/14/96	02/15/97	
Amend Reporting Requirements	CDRH	GE Medical Systems	96P-0306 CP 1	08/15/96	02/19/97	
Laser Light Show	CDRH	Laser Rhythm	96V-0302 VAR 1	08/23/96	02/19/97	
Laser Light Show	CDRH	IJG, Inc. T/A THE BANK	96V-0303 VAR 1	08/23/96	02/19/97	
Laser Light Show	CDRH	Acoustic Works Presentation Systems	96V-0304 VAR 1	08/23/96	02/19/97	
Variance, labeling requirement to allow abbrev. month & year	CDRH	Picker International, Inc.	96V-0323 VAR 1	09/04/96	03/08/97	
Arterial Embolization Devices be reclassified from class 3 to 2	CDRH	Target Therapeutics Inc.	96P-0329 CCP 1	09/06/96	04/11/97	
Reconsider new IDE approval policies and eximer lasers	CDRH	L. McIntosh & Associates Inc.	96P-0339 CP 1	09/13/96	03/19/97	
Laser Light Show	CDRH	A.J. Enterprises	96V-0399 VAR 1	10/17/96	04/20/97	
Variance for High Light Laser System Model K333	CDRH	TriLasers	96V-0397 VAR 1	10/10/96	04/16/97	
Reclassify Cutaneous Oxygen Monitor	CDRH	Radiometer Medical A/s	96P-0435 CCP 1	10/30/96	05/13/97	
Laser light show	CDRH	Manhattan Microwave Communications, Co.	96V-0408 VAR 1	10/29/96	04/27/97	
Variance Steathly Around the Corner Flexible Viewer	CDRH	Olympus America Inc.	96V-0430 VAR 1	11/08/96	05/07/97	
Laser light show application	CDRH	N Effect Production	96V-0432 VAR 1	11/13/96	05/12/97	

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SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Reclassify Ohmeda I-NOvent Delivery System	CDRH	Ohmeda Inc.	96P-0436 CCP 1	11/14/96	05/13/97	
Change in Man. Labeling & Warnings of CNS Delta, SCD & ASD	CDRH	Hydrocephalus Researcher	96P-0444 CP 1	11/15/96	05/17/97	05/30/97
Goode Wrap Massage Cones & Tape Pads be reclassified	CDRH	Goode Wraps, Inc.	96P-0470 CCP 1	12/04/96	07/02/97	
Reclassify Cardiovascular Intra- vascular Filters	CDRH	Nitinal Medical Technologies, Inc.	96P-0482 CCP 1	12/03/96	06/10/97	
Reclassify Cardiovascular Intra- vascular Filters	CDRH	B. Braun Vena Tech	96P-0482 CCP 2	12/03/96	06/10/97	
Laser Light Show	CDRH	Kenney's Light & Sound	96V-0475 VAR 1	12/05/96	06/03/97	
Laser Light Show	CDRH	Rio Suite Hotel & Casino	96V-0476 VAR 1	12/06/96	06/07/97	
Laser Ligh Show Mobolazer	CDRH	Joseph Alisio	96V-0481 VAR 1	12/10/96	06/08/97	
Laser Light Show	CDRH	Lighting Systems Design Inc	96V-0485 VAR 1	12/13/96	06/11/97	
Laser Fantasy International	CDRH	Regal Cinemas Inc.	96V-0495 VAR 1	12/13/96	06/25/97	
Laser Light Show	CDRH	Lars Lighting	97V-0006 VAR 1	01/07/97	07/06/97	
Laser Light Show	CDRH	Pleasuredome	97V-0016 VAR 1	01/13/97	07/14/97	
Variance for laser light show	CDRH	George Carden Circus International	97V-0019 VAR 1	01/15/97	07/15/97	
Laser Light Show	CDRH	Economics & Technology Inc.	97V-0033 VAR 1	01/23/97	07/23/97	
Hip Joint Metal/Ceramic/Ceramic Semi-Constrained Prosthesis	CDRH	CeramTec, A.G.	97P-0048 CCP 1	02/03/97	09/04/97	
Revoke Order Issued to MRT, Inc. Re: Diapulse Device	CDRH COMM	Diapulse Corporation	93P-0065 PRC 1	02/24/97	09/03/97	08/19/97
Laser Light Show, Model Mobolazer ML10-200, ML10-300	CDRH	Paladrome	97V-0070 VAR 1	02/25/97	08/25/97	
Laser Art Display	CDRH	PM Realty Group	97V-0071 VAR 1	02/05/97	08/25/97	
NI to Establish Effective Dates for 31 Class III Preamend	CDRH COMM	E. Benson Hood Laboratories, Inc	88N-0244 PSA 1	02/27/97	08/26/97	
Variance from certain provision of regulations	CDRH	Sulzer Carbomedics Inc.	97P-0085 CP 1	03/06/97	09/06/97	
Lighting Effects	CDRH	Syncor	97V-0086 VAR 1	03/06/97	09/03/97	
Mobolazer ML10-200, ML10-300, ML10-300W, ML10-1000	CDRH	Campion Sales Company, Inc.	97V-0114 VAR 1	03/18/97	09/14/97	06/11/97
Laser Certification & Standards	CDRH	DioLase Corporation	97V-0198 VAR 2	04/01/97	09/28/97	
"Smokeless Cigarette" or "Smokefree Cigarette" "Eclipse"	CDRH GCF	R J Reynolds Tobacco Co.	94P-0456 CP 3	04/18/97	10/15/97	
Advisory opinion on Labeling of Contact Lens Care Products	CDRH	Bausch & Lomb	97A-0173 AP 1	04/23/97	10/20/97	
Laser Light Show	CDRH	Paladrome	97V-0177 VAR 1	04/29/97	10/27/97	

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SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Reclassify Pedicle Screw Spinal Systems to Class II from III	CDRH	American Association of Neurological Surgeons	95N-0176 CP 1	05/12/97	11/09/97	
Laser Light Show, Universal Laser Projector	CDRH	Anthropomorphic Productions Inc.	97V-0193 VAR 1	05/13/97	11/09/97	
Laser Light Show, Universal Laser Projector	CDRH	Anthropomorphic Productions Inc.	97V-0193 VAR 2	05/13/97	11/09/97	
Amend CPG to include category of in vitro products	CDRH COMM	Joint Council of Immunohistochemical Mfr	97P-0196 CP 1	05/14/97	11/10/97	
Activities Related to Hearing Aid Promotion & Advertising	CDRH	Hearing Industries Association	94P-0114 PRC 1	05/28/97	11/26/97	
Endolymphatic shunt tube with valve change in classification	CDRH	E Benson Hood Laboratories Inc	97P-0210 CCP 1	05/28/97	12/24/97	
Laser Light Show re: Gemini Lasers	CDRH	Gemini Laser Corporation	97V-0230 VAR 1	06/06/97	09/08/97	
OMNISCAN Laser Projection System, Model 2000	CDRH	Redlin Arts Center	97V-0236 VAR 1	06/11/97	12/09/97	
3D multimedia theater presentation incorporating a Lightspee	CDRH	COSI, Teledo	97V-0237 VAR 1	06/12/97	12/09/97	
Mammomat 300/3000 x-rays units breast cancer diag & screening	CDRH	Siemens Medical Systems, Inc.	97V-0240 VAR 1	06/13/97	12/10/97	
Omniscan Laser Projection System, Model 2000	CDRH	Hansen Planetarium	97V-0246 VAR 1	06/17/97	12/15/97	
Advisory Opinion, Preemption of NY State Tissue Bank License	CDRH COMM	Advanced Tissue Sciences, Inc.	97A-0247 AP 1	06/17/97	12/15/97	
Laser Light Show	CDRH	Photnic Laser Light Shows	97V-0248 VAR 1	06/17/97	12/15/97	
Omniscan Laser Projection System, Model 2000	CDRH	Redline Arts Center	97V-0246 VAR 2	06/18/97	12/15/97	
Laser light show produced with CSD 4100 laser projector	CDRH	Friends of the Douglass Theatre Complex	97V-0286 VAR 1	07/08/97	01/04/98	
Reclassify specific group of devices, Thermal Reg. Systems	CDRH	Augustine Medical Inc	97P-0309 CCP 1	07/21/97	01/18/98	
Two-Year Rule for IDE's & PMA's for Orthopedic Spinal Dev.	CDRH COMM	United States Surgical Corporation	97P-0315 CP 1	07/23/97	01/21/98	
Incubation cycle antimicrobial susceptibility	CDRH	BioMerieux Vitek, Inc,	97P-0313 CCP 1	07/24/97	01/20/98	
Premarket Aproval of ThinPrep 2000 Processor	CDRH	Trylon Corporation	97M-0254 PRC 1	07/28/97	01/25/98	

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Premarket Aproval of ThinPrep 2000 Processor	CDRH	Dartmouth-Hitchcock Medical Center	97M-0254 PRC 2	07/29/97	01/25/98	
Premarket Aproval of ThinPrep 2000 Processor	CDRH	Medical Procedures Center P C	97M-0254 PRC 3	07/29/97	01/25/98	
Premarket Aproval of ThinPrep 2000 Processor	CDRH	Cytology West Inc	97M-0254 PRC 4	07/30/97	01/27/98	
Premarket Aproval of ThinPrep 2000 Processor	CDRH	Obstetrics & Gynecology	97M-0254 PRC 5	07/31/97	01/27/98	
Premarket Aproval of ThinPrep 2000 Processor	CDRH	College of Medicin/UCI Med Center Ob&Gyn	97M-0254 PRC 6	07/31/97	01/27/98	
Premarket Aproval of ThinPrep 2000 Processor	CDRH	Gary Edwards, M.D.	97M-0254 PRC 7	08/04/97	01/31/98	
Reclassify Home Uterine Activity Monitors from III to II	CDRH	Corometrics Medical Systems, Inc.	97P-0350 CCP 1	08/15/97	03/17/98	
Laser Light Show, Mobolazer ML10-200, ML10-300, ML10-300W	CDRH	Spellbound, Inc.	97V-0348 VAR 1	08/18/97	02/15/98	
Laser light show application	CDRH	Stage One Supply Inc	97V-0351 VAR 1	08/18/97	02/15/98	
Variance for Laser Light Show	CDRH	Bartels & Bartels	97V-0355 VAR 1	08/18/97	02/16/98	
Laser Light show	CDRH	Spellbound Inc	97V-0356 VAR 1	08/19/97	02/16/98	
Reclassification Petition for Constrained Elbow Joint Prosth	CDRH	Orthopedic Surgical Manufacturers Assn.	97P-0364 CCP 1	08/21/97	03/23/98	
Two-Year Rule for IDE's & PMA's for Orthopedic Spinal Dev.	CDRH COMM	Spinetech Inc.	97P-0315 CP 2	08/22/97	02/22/98	
Irradiation of human body/remote interlock connector	CDRH	Trans Medica	97V-0366 VAR 1	08/26/97	02/22/98	
Laser Light Show	CDRH	Silver Legacy Casino	97V-0376 VAR 1	09/05/97	03/04/98	
Interpret the terms "manufacturer" or 'Remanufacturer'	CDRH	Health Industry Manufacturers Assn	97P-0377 CP 1	09/05/97	03/04/98	
Laser System Scans CW at 0-30,000 pps, amplitude 90 deg optic	CDRH	Regal Cinemas Inc.	97V-0419 VAR 1	10/03/97	04/04/98	
Laser Light Show	CDRH	Haunted Mansion Inc.	97V-0422 VAR 1	10/07/97	04/06/98	
Projector for a laser light show	CDRH	Tri Lasers	97V-0425 VAR 1	10/09/97	04/07/98	
Laser Light Show	CDRH	Carrot Top Inc.	97V-0426 VAR 1	10/09/97	04/07/98	
Regulate, Investigate, & enforce man-made sources of radiation	CDRH	Thomas Daniel Clark	97P-0434 CP 1	10/21/97	04/21/98	
Variance for LaserXpress	CDRH	Trans Florida Restaurant Association	97V-0452 VAR 1	11/05/97	05/04/98	
Laser Light Show	CDRH	CourtYards of Mackinaw	97V-0455 VAR 1	11/06/97	05/05/98	

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Laser Light Show	CDRH	Laser Onyx	97V-0470 VAR 1	11/10/97	05/12/98	
Laser Light Show	CDRH	CJ Deluca	97V-0471 VAR 1	11/13/97	05/13/98	
Laser Light Show	CDRH	Laser Entertainment Co.	97V-0475 VAR 1	11/17/97	05/17/98	
Safety of UVA Tanning Unit labeling and Use	CDRH	Rapid Precision Testing	97P-0478 CP 1	11/18/97	05/18/98	
Mobolazer ML10-200, ML10-300, ML10-300W, ML10	CDRH	The Guy Michaels Production Group, Inc.	97V-0482 VAR 1	11/21/97	02/19/98	
Laser Light Show	CDRH	Productions Design Associates Inc.	97V-0490 VAR 1	11/24/97	05/25/98	
Laser Light Show	CDRH	The Peter Schmitt Company	97V-0491 VAR 1	11/24/97	05/25/98	
Laser light show, model mobolaser ML10-200, ML10-300, ML10-3	CDRH	Jon Michaels Productions	97V-0492 VAR 1	11/28/97	05/27/98	
OTC Drugs Warning Label for Pregnant and Nursing Women	CDER/OTC	Public Citizen/Health Research Group	82N-0050 CP 7	6/30/83	12/28/83	04/24/84
Sunscreen Drug Products	CDER/OTC	EM Industries Inc.	78N-0038 CP 1	07/19/84	01/15/85	08/02/85
OTC Laxative	CDER/OTC	C. B. Fleet Company	78N-036L CP 7	11/12/87	05/10/88	10/26/89
OTC Laxative	CDER/OTC	C. B. Fleet Company	78N-036L CP 8	11/12/87	05/10/88	10/26/89
OTC Cough-Cold General Comments & Combinations	CDER/OTC	Public Citizen/Health Research Group	76N-052G CP 1	12/15/88	06/14/89	10/10/89
Vaginal Drug Products for OTC Use	CDER/OTC	Purdue Frederick Co.	82N-0291 CP 1	12/23/88	06/22/89	03/22/90
Sunscreen Drug Products for OTC Use	CDER/OTC	BASF AG	78N-0038 CP 2	05/25/89	11/24/89	12/11/89
Sunscreen Drug Products	CDER/OTC	Haarmann & Reimer Corp.	78N-0038 CP 3	07/27/90	01/28/91	
OTC Laxative	CDER/OTC	The Purdue Frederick Co.	78N-036L CP 11	07/10/91	01/06/92	
OTC Weight Control Drug Products for Human Use	CDER/OTC	Thompson Medical Co., Inc.	81N-0022 CP 14	10/07/91	01/06/82	
OTC Digestive Aid Drug Products for Human Use	CDER/OTC	Requa, Inc.	81N-0106 CP 2	10/18/91	04/15/92	
External Analgesic Drug Products for OTC Human Use	CDER/OTC	Combe, Inc.	78N-301H CP 2	01/28/92	07/27/92	11/24/93
Drug Products for Dandruff, Seborrheic Dermatitis & Psoriasis	CDER/OTC	Combe, Inc.	82N-0214 CP 1	01/28/92	07/27/92	
Conduct survey to determine adverse reaction from aspirin	CDER/OTC	Stanley E Cohen	92P-0116 CP 1	03/05/92	09/08/92	11/30/92
OTC External Analgesic Drug Products	CDER/OTC	GenDerm Corporation	78N-0301 CP 9	03/13/92	09/14/92	10/05/92
OTC Internal Analgesic, Antipyretic & Antirheumatic	CDER/OTC	Aspirin Foundation of America, Inc.	77N-0094 CP 9	04/13/92	10/13/92	10/15/92
OTC Antiperspirant	CDER/OTC	Glen Scott, M.D.	78N-0064 CP 2	06/05/92	12/02/92	04/01/93
Amend OTC Drug Review Policy Regarding Foreign Ingredients	CDER/OTC	European-American Phytomedicines Coalition	92P-0309 CP 1	07/24/92	01/23/93	

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Oral Health Care Drug Products for OTC Human Use	CDER/OTC	Robell Research Corp.	81N-0033 CP 2	09/10/92	03/10/93	08/26/93
OTC Digestive Aid Drug Products for Human Use	CDER/OTC	Sterling Health; Div. Sterling Winthrop	81N-0106 CP 3	10/26/92	04/26/93	11/18/93
Safety & Efficacy of Lactase Enzyme/Fungal Sources	CDER/OTC	Sterling Health; Div. Sterling Winthrop	92P-0408 CP 1	10/26/92	04/26/93	11/18/93
OTC Internal Analgesic, Antipyretic & Antirheumatic	CDER/OTC	Brigham & Women's Hospital	77N-0094 CP 10	12/30/92	06/28/93	06/12/96
OTC Antiperspirant	CDER/OTC	Patricia Sanders	78N-0064 CP 3	01/08/93	07/07/93	04/01/93
Ban and/or Relabeling of Antidiarrheal Drugs	CDER/OTC	Public Citizen/Health Research Group	93P-0011 CP 1	01/11/93	07/12/93	07/09/93
Conduct Survey to Determine Adverse Reaction from Aspirin	CDER/OTC	Stanley E. Cohen	92P-0116 PRC 1	01/26/93	07/28/93	
Topical Antimicrobial Drug Products for OTC Human Use	CDER/OTC	Mitech Laboratories, Inc.	75N-183F CP 1	04/16/93	10/13/93	
OTC Laxative	CDER/OTC	CIBA Consumer Pharmaceuticals	78N-036L CP 15	06/15/93	12/13/93	02/15/95
OTC Weight Control Drug Products for Human Use	CDER/OTC	Caprice-Greystoke	81N-0022 CP 16	11/24/93	05/23/94	01/26/94
OTC External Analgesic Drug Products	CDER/OTC	Thompson Medical Co.,Inc.	78N-0301 CP 10	01/05/94	07/05/94	
OTC External Analgesic Drug Products	CDER/OTC	Thompson Medical Co., Inc.	78N-0301 CP 11	04/18/94	10/17/94	
Ingrown Toenail Drug Products for OTC Human Use	CDER/OTC	Schering-Plough Healthcare Products	80N-0348 CP 1	05/25/94	11/22/94	
Amend Monograph to include Valerian as OTC Sleep-aid Product	CDER/OTC	European-American Phytomedicines Coalition	94P-0215 CP 1	06/08/94	12/05/94	
OTC Internal Analgesic, Antipyretic & Antirheumatic	CDER/OTC	Brigham & Woman's Hospital	77N-0094 CP 12	06/09/94	12/06/94	06/12/96
Sunscreen Drug Products	CDER/OTC	Estee Lauder, Inc.	78N-0038 CP 6	07/27/94	01/23/95	
Amend monograph to include Valerian as OTC sleep-aid Product	CDER/OTC	American Vitamin Products, Inc.	94P-0215 CP 2	07/28/94	01/24/95	
Amend monograph to include Valerian as OTC sleep-aid Product	CDER/OTC	American Vitamin Products, Inc	94P-0215 PSA 1	07/28/94	01/24/95	
Antifungal Drug Products for OTC Human Use	CDER/OTC	Mitech Laboratories, Inc.	80N-0476 CP 5	08/25/94	02/21/95	
Homeopathic Drug meet the same requirement as Nonhomeopathic Drug	CDER/OTC	Stephen Barrett, M.D.,	94P-0316 CP 1	08/31/94	02/27/95	02/09/95
OTC Weight Control Drug Products for Human Use	CDER/OTC	Caprice-Greystoke, Ltd.	81N-0022 PRC 1	10/21/94	04/19/95	
OTC Laxative	CDER/OTC	Nonprescription Drug Manufacturers Association	78N-036L CP 19	11/14/94	05/15/95	

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
OTC Weight Control Drug Products	CDER/OTC	Caprice-Greystoke, Ltd.	81N-0022 PSA 1	12/14/94	06/13/95	
Health-Care Antiseptic Drug Products for OTC Human Use	CDER/OTC	Mitech Laboratories, et al	75N-183H CP 1	01/31/95	07/31/95	
OTC Weight Control Drug Products for Human Use	CDER/OTC	Caprice-Greystoke, Ltd.	81N-0022 PRC 1	02/02/95	08/01/95	
OTC Weight Control Drug Products for Human Use	CDER/OTC	Caprice-Greystoke, Ltd.	81N-0022 PSA 1	02/02/95	08/01/95	
Nailbiting & Thumbsucking Deterrent Drug Product for OTC Use	CDER/OTC	Oakhurst Company	80N-0146 CP 3	02/10/95	08/14/95	
Treatment & prevention of Nocturnal Leg Muscle Cramp for OTC Use	CDER/OTC	Ciba Self-Medication, Inc	95P-0048 CP 1	02/22/95	08/21/95	
Skin Protectant Drug Proposed Rulemaking for Diaper Rash	CDER/OTC	Procter & Gamble	78N-021D CP 1	03/09/95	09/05/95	
Change Labeling for OTC Caffeine 100mg & 200mg	CDER/OTC	Caprice-Greystoke, Ltd.	95P-0085 CP 1	03/29/95	09/25/95	
Oral Health Care Drug Products for Oral Human Use	CDER/OTC	SmithKline Beecham Consumer HealthCare	81N-0033 CP 4	04/12/95	10/10/95	
Amend Monograph on Antiemetic Drug Products for OTC Human Use	CDER/OTC	European-American Phytomedicines Coalition	95P-0145 CP 1	05/26/95	11/22/95	
OTC Laxative	CDER/OTC	C. B. Fleet Company, Inc.	78N-036L CP 20	06/09/95	12/06/95	
OTC Laxative	CDER/OTC	C. B. Fleet Company, Inc.	78N-036L CP 21	06/09/95	12/06/95	
Health-Care Antiseptic Drug Products for OTC Human Use	CDER/OTC	3M Health Care	75N-183H CP 2	06/16/95	12/13/95	
Topical Antimicrobial Drug Products for OTC Human Use	CDER/OTC	West Agro, Inc.	75N-183F CP 2	06/19/95	12/13/95	
Skin Protectant Drug Products to OTC, Astringent Drug Products	CDER/OTC	Allergan, Inc.	78N-021A CP 1	07/06/95	01/03/96	
OTC External Analgesic Drug Products	CDER/OTC	Thompson Medical Co.,Inc.	78N-0301 CP 12	07/13/95	01/09/96	
Orally Administered Menstrual Drug Products for OTC Use	CDER/OTC	Direct Pharmaceuticals Limited	82N-0165 CP 3	07/24/95	01/20/96	
Waiver for Feminine Gold External Topical Analgesic Lotion	CDER/OTC	Au Pharmaceuticals Inc.	95P-0273 CP 1	08/17/95	02/14/96	10/13/95
Skin Protectant Drug Proposed Rulemaking for Diaper Rash	CDER/OTC	Smith & Nephew United, Inc	78N-021D CP 2	12/21/95	06/19/96	
OTC Laxative	CDER/OTC	Procter & Gamble	78N-036L CP 22	03/29/96	09/29/96	
Denture Cleansers - Antimicrobial -type Claims	CDER/OTC CDRH	Kleinfeld, Kaplan & Becker	96A-0273 AP 1	08/01/96	02/01/97	

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Cetylpyridinium Chloride as ingredient in household handsoap	CDER/OTC	Comprehensive Technology Center	96P-0312 CP 1	08/29/96	02/25/97	
Sunscreen Drug Products	CDER/OTC	Morgan,Lewis & Bockius	78N-0038 CP 7	11/15/96	05/17/97	
Add Clotrimazole 1.0% for Treatment of Athlete's Foot etc.	CDER/OTC	Schering-Plough HealthCare Products	96P-0460 CP 1	12/02/96	05/31/97	09/18/97
Sunscreen Drug Products	CDER/OTC	Procter & Gamble	78N-0038 CP 8	06/25/97	12/23/97	
Sunscreen Drug Products	CDER/OTC	Schering-Plough HealthCare Products	78N-0038 CP 9	07/07/97	01/04/98	
Anticaries Drug Products for OTC Human Use	CDER/OTC	Tom's of Maine	80N-0042 PSA 6	09/10/97	03/11/98	
Anticaries Drug Products for OTC Human Use	CDER/OTC	Amway Corporation	80N-0042 CP 1	10/08/97	04/06/98	
OTC Internal Analgesic, Antipyretic & Antirheumatic	CDER/OTC	Whitehall-Robins	77N-0094 CP 13	11/28/97	05/27/98	
Levsinex and Levsinex with Phenobarbital to Remain on Market	CDER	Kremers-Urban Co.	77P-0400 CP 1	11/25/77	05/24/78	
Revoke Requirement of Expiration Dating on Medical Gases	CDER	Compressed Gas Association, Inc.	79P-0067 CP 1	02/26/79	09/02/79	03/19/82
Amend ANDA 85-515 Premarin (R) with Methyltestosterone	CDER	Ayerst Labs	80P-0466 CP 1	11/17/80	05/18/81	
Revise Current Regulations on IND Pt. 312	CDER	PMA	80P-0480 CP 1	11/26/80	05/26/81	
Inactive Ingredients Labeling for Prescription and OTC Drugs	CDER	Public Citizen/Health Research Group	83P-0418 CP 1	12/12/83	06/11/84	06/20/84
Remove Prescription and OTC Drugs Containing Vioform	CDER	Public Citizen/Health Research Group	85P-0344 CP 1	07/25/85	02/18/86	
Certain Estrogen-Containing Drugs for Oral or Parenteral Use	CDER	Ayerst Labs	76N-0356 CP 1	06/05/86	12/03/86	
Pilot Project Re: Drug Substance Applications (DSA)	CDER	Generic Pharm Ind Assn.	87P-0151 CP 1	04/23/87	10/20/87	04/14/88
Use of Versed (Midazolam) by Patients 60 years or older	CDER	Public Citizen/Health Research Group	88P-0059 CP 1	02/16/88	04/18/88	10/21/88
Oligosaccharide/Neomycin Sulfate	CDER	Pharma-Tek	87D-0315 PSA 1	08/12/88	02/09/89	
Sterile Neomycin Sulfate for Parenteral Use	CDER	Pharma-Tek	79N-0151 PSA 1	08/12/88	02/08/89	05/02/89
Neomycin Sulfate	CDER	Pharma-Tek	79N-0155 PSA 1	08/12/88	02/08/89	
OTC Internal Analgesic, Antipyretic & Antirheumatic Products	CDER	Health Research Group/Public Citizen	77N-0094 CP 6	12/02/88	06/01/89	03/08/95
Sterile Neomycin Sulfate for Parenteral Use	CDER	Pharma-Tek Inc.	79N-0151 PSA 2	12/30/88	06/29/89	05/02/89
Prescription Drug Advertisements Directed to Consumers	CDER	Sonnenreich & Reccograndi	89P-0505 CP 1	11/29/89	05/29/90	05/23/90
Withdraw Approval of ANDA for Propranolol HCL by Inwood Laboratories	CDER	Wyeth-Ayerst Labs.	90P-0072 CP 1	02/16/90	08/13/90	08/06/90

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Premarin Label be Declared as False & Misleading	CDER	Barr Laboratories, Inc.	90P-0081 CP 1	02/26/90	08/24/90	01/09/91
Ban the Use of Phenobarbital	CDER	National Network to Prevent Birth Defects	90P-0166 CP 1	05/01/90	10/30/90	
Ban Ergoloid Mesylates (Hydergine and Others)	CDER	Public Citizen/Health Research Group	91P-0053 CP 1	02/14/91	08/13/91	08/12/91
Advisory Opinion Regarding Solvents in Drug Manufacturing	CDER	BioMarine Technologies, Inc/	91A-0222 AP 1	06/11/91	12/08/91	
Advertising of prescription drugs	CDER	King & Spalding	91P-0227 CP 1	06/14/91	12/16/91	04/11/92
Ban the Advertising of Prescription Drugs	CDER	National Association of Pharmaceutical Manufacturers	91P-0337 CP 1	08/13/91	02/13/92	04/11/92
Issue a definitive interpretation of the CGMP	CDER	Burroughs Wellcome Co.	91P-0433 CP 1	10/22/91	04/20/91	05/02/92
Tooth Whitening Systems and/or Tooth Whitening Products	CDER/CFSAN	Telebrands	91P-0476 CP 1	11/27/91	05/26/92	10/19/92
Tooth Whitening Systems and/or Tooth Whitening Products	CDER/CFSAN	Howe Chemical Labs. and Crescent Mfgs.	91P-0476 CP 2	11/27/91	05/26/92	10/19/92
Advisory Opinion Regarding Dispensing of Methylsulfonylmethane (MSM) Withing State of Oregon	CDER	Oregon Department of Justice	91A-0488 AP 1	12/02/91	06/01/92	
Tooth Whitening Products with carbamide peroxide	CDER/CFSAN	Professional-Use Tooth Whitening Mfg.	92P-0123 CP 1	03/05/92	09/08/92	10/19/92
Use of Administrative Procedure Act	CDER	Washington Legal Foundation	92P-0125 CP 1	03/05/92	09/08/92	09/19/92
Withdraw marketing approval for doxylamine succinate	CDER	Association of Birth Defect Children, Inc.	92P-0235 CP 1	05/27/92	11/24/92	
Labeling for Nicotine Delivery Products, Gum & Patch	CDER	Public Citizen/Health Research Group	92P-0240 CP 1	06/03/92	11/30/92	11/23/92
Root Canal Fill Material/Sealer Fulfill NDA & PMA Requirement	CDER/CDRH	N2 Products Corporation	92P-0262 CP 1	06/17/92	12/15/92	
Determine Bendectin not withdrawn for safety/effective reasons	CDER	Pharmaceutical Development & Licensing Ltd	92P-0274 CP 1	06/29/92	12/28/92	
Advisory Opinion with Respect to Transfer of Drugs from Not-for-Profit Hospital to its Affiliated Retail Pharmacy or its Affiliated Health Care System	CDER	Woods, Rogers & Hazelgrove ,	92A-0394 AP 1	10/09/92	04/11/93	04/19/93
Written Procedures for Submitting Efficacy Sup./Cancer AIDS	CDER	Adria Laboratories	92P-0505 CP 1	12/22/92	06/21/93	06/21/93

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Reverse Determination Re: Albuterol Sulfate Solution Mfg. Dey Labs	CDER	Schering-Plough Corp.	93P-0141 CP 1	04/05/93	10/04/93	09/28/83
Amend Regulations regarding Homeopathic Drugs	CDER	American Homeopathic Pharmaceutical Assn.	94P-0018 CP 1	01/24/94	07/25/94	06/24/94
Uniform Wording in All IND Acknowledgement Letters	CDER/CBER	Burroughs Wellcome, Co.	94P-0035 CP 1	02/15/94	08/15/94	08/03/94
Current GMP in Mfg, Process, Packing/Holding: revision Label	CDER	NEMA et al	88N-0320 PRC 1	05/04/94	10/31/94	08/04/94
Current GMP in Mfg, Process, Packing/Holding: revision Label	CDER	Generic Pharmaceutical	88N-0320 PRC 2	05/06/94	11/02/94	08/04/94
Broaden probe into hGH	CDER	The Foundation on Economic Trends	94P-0319 CP 1	09/01/94	02/28/95	03/08/95
Broaden probe into illegal use of hGH	CDER	The Foundation on Economic Trends	94P-0320 CP 1	09/01/94	02/28/95	03/08/95
CGMP for Finished Pharmaceuticals	CDER	Compressed Gas Assn., Inc.	94P-0426 CP 1	11/28/94	05/30/95	05/07/95
Establish the Proper Composition of Conjugated Estrogens	CDER	Wyeth-Ayerst Laboratories	94P-0429 CP 1	12/01/94	05/30/95	05/31/95
Stay of Action of Approval of ANDAs for Conjugated Estrogens	CDER	Wyeth-Ayerst Laboratories	94P-0430 CP 1	12/01/94	05/30/95	01/17/95
Debar Mark B. Perkal; Notice of Opportunity for Hearing	CDER	Dr. Mark B. Perkal	93N-0253 AST 1	04/14/95		04/29/97
Prescription Drug Advertisements	CDER/COMM	Sonnenreich, Roccograndi & Woo	95P-0104 CP 1	04/24/95	10/23/95	10/05/95
Albuterol Inhalation Aerosols (Metered Dose Inhalers)	CDER/COMM	3M Pharmaceuticals/3M Co.	95P-0153 CP 1	06/05/95	12/04/95	12/01/95
Exempt Medical Gases from the Requirements of 21 CFR 205	CDER/COMM	Compressed Gas Association, Inc.	95P-0188 CP 1	06/26/95	12/23/95	12/12/95
Cease Regs on Prescription Drug Advertisment to Consumers	CDER	Washington Legal Foundation	95P-0224 CP 1	07/20/95	01/27/96	04/24/96
Revise "Approved Drug Products" (Known as "Orange Book")	CDER/COMM	Kleinfeld, Kaplan & Becker	95P-0262 CP 1	08/11/95	02/07/96	01/30/96
Issue a guidance/Refuse to allow an IND for Cyclophosphamide	CDER	Kleinfeld, Kaplan & Becker	95P-0338 CP 1	10/13/95	04/14/96	04/05/96
ANDA for Dextromephorphan Hydrobromide & Tripelennamine Hydrochloride	CDER	Bock Pharmacal Co.	95P-0345 CP 1	10/23/95	12/23/95	
ANDA Suitability for 1 mg Azatadine Maleate & 30 mg Phenylephrine Hydrochloride	CDER	Bock Pharmacal Co.	95P-0351/CP 1	10/30/95	12/29/95	
Cease Regs. On Prescription Drug Advertisments to Consumers	CDER/COMM	Consumer Alert	95P-0224 CP 2	11/17/95	05/15/96	04/24/96

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Warning on all Calcium Channel Blocking Drugs	CDER	Public Citizen	95P-0376 CP 1	11/17/95	05/15/96	05/02/96
Modify Advice Bioequivalence of generic ammonium lactate	CDER	Westwood Squibb Pharmaceuticals, Inc.	95P-0379 CP 1	11/20/95	05/25/96	
Refrain from approval ANDA for aluminum hydroxide dried gel	CDER	Kleinfeld, Kaplan & Becker	95P-0382 CP 1	11/22/95	05/20/96	05/24/96
Disclosure of Results of Statistical Studies re: INDs	CDER	Washington Legal Foundation	96P-0001 CP 1	12/29/95	06/30/96	07/02/96
Listing of Transderm-Scop in Approved Drug Products	CDER	Sano Corporation	96P-0109 CP 1	04/02/96	09/29/96	09/30/96
ANDA for Effervescent Lactulose Crystals	CDER	Bennett and Company	96P-0155 CP 1	05/15/96	07/16/96	
Refrain from granting exclusivity to NDAs for Fexofenadine	CDER	Olsson, Frank & Weeda	96P-0157 CP 1	05/17/96	11/21/96	11/07/96
ANDA Suitability for nifedipine extented-release tablet	CDER	Bayer Corporation	95P-0067 PRC 1	05/24/96	11/25/96	
ANDA for Nifedipine Extended-release Capsules	CDER	Bayer Corporation	95P-0326 PRC 1	05/30/96	12/01/96	
Adopt Bioequivalence Testing Guidelines for Iopamidol Inject	CDER	Bracco Diagnostics Inc.	96P-0187 CP 1	06/06/96	12/03/96	12/02/96
Withdrawal Norplant's approval for sale in the United States	CDER	Population Research Institute	96P-0215 CP 1	06/27/96	12/24/96	12/23/96
Adopt Bioequivalency Requirements for Propafenone Tablets	CDER	Knoll Pharmaceutical Company	96P-0243 CP 1	07/08/96	01/05/97	01/10/97
Adopt Bioequivalence Testing Guidelines for Iopamidol Inject	CDER	Bracco Diagnostics, Inc.	96P-0187 PSA 1	07/24/96	01/20/97	
ANDA for Terazosin Hydrochloride Tabs be Eligible for Approval	CDER	Novopharm Limited	96P-0268 CP 1	07/29/96	01/26/97	
Warning on all Fluoroquinolone Antibiotics	CDER	Public Citizen Health Research Group	96P-0301 CP 1	08/07/96	02/18/97	02/05/97
Minocycline HCI tablets withdrawn from sale/efficacy reasons	CDER	Clausen & Associates	96P-0316 CP 1	08/30/96	03/04/97	
Consider solid oral dosage form drug products as same dosage	CDER	National Assn of Pharmaceutical Manufacturers	96P-0317 CP 1	09/05/96	03/04/97	01/14/97
CSP and all forms or silver marketed for human & animal con.	CDER	Rosemary Jacob	96P-0342 CP 1	09/10/96	03/19/97	03/11/97
Erroneous Designation of Neoral (Cyclo. for Mecroemulsion)	CDER	Sandoz Pharmaceuticals Corporation	96P-0459 CP 1	11/27/96	05/28/97	05/23/97

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Erroneous Designation of Neoral (Cyclo. for Mecroemulsion)	CDER	Sandoz Pharmaceuticals Corporation	96P-0459 PSA 1	11/27/96	06/18/97	
Powder filled hard gelatin capsule suitable for abbrev new drug application	CDER	Olsson Frank & Weeda	96P-0494 CP 1	12/18/96	06/17/97	
Prednisolone Sodium Phosphate Oral Chewable Tablet	CDER	We Pharmaceuticals, Inc.	96P-0498 CP 1	12/20/96	02/25/97	
Prednisolone Sodium Phosphate Oral Liquid for ANDA	CDER	We Pharmaceuticals, Inc.	96P-0499 CP 1	12/20/96	02/25/97	
Withhold approval of NDAs/ANDAs involving Paclitaxel	CDER COMM	Oregon Natural Resources Council Action	97P-0008 CP 1	01/03/97	07/09/97	07/09/97
Stay Action on NDAs/ANDAs involving Paclitaxel	CDER COMM	Oregon Natural Resources Council Action	97P-0009 PSA 1	01/03/97	07/09/97	07/09/97
Questran Tablets (Oral Cholestyramine Tablets)	CDER COMM	Hyman, Phelps & McNamara, PC	97P-0028 CP 1	01/17/97	07/17/97	
Therapeutic equivalence evaluation to an antibiotic drug	CDER COMM	Fox, Bennett & Turner	97P-0037 CP 1	01/24/97	07/28/97	07/21/97
Harmonize the agency's acceptable document delivery methods.	CDER COMM	McKenna & Cuneo, L.L.P.	97P-0044 CP 1	02/04/97	08/04/97	08/12/97
Deny Exclusivity to Nicotine Patch Sub Products for OTC Use	CDER COMM	Greenberg Traurig et al	97P-0079 CP 1	02/27/97	08/30/97	08/07/97
Drug acetaminophen tend to deplete glutathione for HIV-infections	CDER	Department of Genetics & Medicine	97P-0102 CP 1	03/06/97	09/06/97	
Modify Package Labeling for Ultane (Sevoflurane) Anesthetic	CDER COMM	University of California	97P-0093 CP 1	03/10/97	09/06/97	08/18/97
Refrain from granting AVITA an "A" rating, Orange Book	CDER	Ortho Pharmaceutical Corp.	97P-0094 CP 1	03/10/97	09/06/97	08/26/97
ANDA Suitability for a topical corticosteriod drug product	CDER	Ferndale Laboratories, Inc.	97P-0101 CP 1	03/13/97	09/10/97	
Classify all Cigarette Products as Drugs	CDER COMM/GCF	R. J. Reynolds Tobacco Co.	94P-0069 CP 2	04/18/97	10/15/97	11/06/97
Regulate Cigarettes Containing Nicotine as Drugs or Devices	CDER COMM	R. J. Reynolds Tobacco Co.	94P-0077 CP 3	04/18/97	10/15/97	11/06/97
ANDA suitability for diltiazem hcl extended tablet, 120 180,	CDER	Labopharm, Inc.	97P-0195 CP 1	05/14/97	07/13/97	
First Co. to submit ANDA for Form 1 Raritidine Hydrochloride	CDER COMM	Geneva Pharmaceuticals, Inc	97P-0207 CP 1	05/21/97	11/17/97	11/07/97

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Exclusivity for ANDA 74-023, Ranitidine Hydrochloride	CDER COMM	Genpharm, Inc.	97P-0216 CP 1	06/02/97	08/02/97	11/07/97
ANDA 30mg/mL Ketorolac Tromethamine Injection	CDER	Bedford Laboratories	97P-0227 CP 1	06/04/97	09/09/97	
Listed drug capsules change in dosage form and strengths	CDER	Ethypharm and Pharma Consult Inc.	97P-0225 CP 1	06/06/97	12/03/97	
Issue a final approval for its ANDA 74-488 effective 7/10/97	CDER	Granutec, Inc.	97P-0235 CP 1	06/11/97	08/11/97	12/08/97
Approve ANDA 74-662 for Ranitidine Hydrochloride	CDER	Boehringer Ingelheim Corporation	97P-0244 CP 1	06/16/97	09/16/97	12/03/97
ANDA Suitability for Paclitaxel Injection 210mg/35ml, 450mg	CDER	Genesia Laboratories, Ltd	97P-0245 CP 1	06/17/97	09/16/97	
ANDA Suitability for Lyophilized Leucovorin Calcium Injection	CDER	Bigmar Inc.	97P-0303 CP 1	07/15/97	09/13/97	
Approve TorPharm's ANDA for a Form 1 Ranitidine HCL Product	CDER COMM	TorPharm	97P-0307 CP 1	07/18/97	01/14/98	12/19/97
Withdraw approval Intramuscular for Injectable Iron Dextran	CDER	Luitpold Pharmaceuticals, Inc.	97P-0324 CP 1	07/28/97	01/26/98	01/23/98
Premarin Conjugated Estrogens must identify active ingredient	CDER COMM	Duramed Pharmaceuticals Inc.	97P-0327 CP 1	07/29/97	01/27/98	01/23/98
Calcium Chloride Injection 10%, USP Plastic Syringe	CDER	Abbott Laboratories	97P-0328 CP 1	07/29/97	01/27/98	01/23/98
ANDA; Application for nifedipine extended-release tablets.	CDER	Biovail Corporation International	97P-0334 CP 1	08/04/97	02/10/98	
Approve TorPharm's ANDA for a Form 1 Ranitidiny HCL Product	CDER COMM	TorPharm, Inc.	97P-0307 CP 2	08/07/97	02/03/98	01/20/98
Acetaminophen 400 mg in Combo w/ 5,7.5 & 10 mg of Hydrocodon	CDER COMM	Lachman Consultant Services Inc.	97P-0346 CP 1	08/15/97	02/14/98	
ANDA Suitability for Ranitidine Effervescent 37.5mg tablets	CDER	Thomas Blake, R.Ph.	97P-0372 CP 1	09/03/97	11/02/97	
Require special bioequivalence study for ANDA verapamil HCL	CDER	Wyeth-Ayerst Research	97P-0386 CP 1	09/10/97	12/11/97	
ANDA for sublingual tablet formulation of albuterol sulfate	CDER	Richard Hamer Associates, Inc.	97P-0387 CP 1	09/11/97	12/11/97	
ANDA Suitability for Ranitidine Effervescent 75 mg tablets	CDER	Thomas Blake, R.Ph.	97P-0402 CP 1	09/15/97	12/1597	

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
ANDA Suitability for Famotidine Effervescent 5 mg tablets	CDER	Thomas Blake, R.Ph.	97P-0403 CP 1	09/15/97	12/1597	
ANDA Suitability for Famotidine Effervescent 10 mg tablets	CDER	Thomas Blake, R.Ph.	97P-0404 CP 1	09/15/97	12/1597	
ANDA Vecuronium Bromide for Injection, 4mg lyophilized vial	CDER	Abbott Laboratories	97P-0391 CP 1	09/16/97	12/15/97	
ANDA for 40 mL fill volume of Methotrexate Sodium Injection	CDER	Bigmar Inc	97P-0400 CP 1	09/15/97	12/15/97	
Questran & Questran Light (Cholestyramine for Oral Suspension)	CDER	Rohm & Haas Company	97P-0408 CP 1	09/24/97	03/24/98	
Rescind FDA's Acceptance for Filing of Adalat CC by Elan Pharm.	CDER	Bayer AG of Leverkusen & Bayer Corp.	97P-0340 PRC 1	09/29/97	03/29/98	
ANDA for Acyclovir Tablets, 200 mg	CDER	Apotex Corp.	97P-0413 CP 1	09/26/97	03/29/98	
Precription Drug Products; Levothyroxine Sodium	CDER	Mason, Taylor & Colicchio	97N-0314 CP 1	10/14/97	04/13/98	
Amend Strenth in fludeoxyglucose Injection	CDER	Dept. Of Nuclear Medicine	97P-0432 CP 1	10/21/97	04/19/98	
Clarify Specific data for approval of abbreviated new drug applications	CDER	Allergan Inc.	97P-0429 PSA 1	10/22/97	04/20/98	
Anti-Nauseant Drug Withdrawn from Approved Drug List	CDER	CATO Research	97P-0437 CP 1	10/22/97	04/27/98	
ANDA Suitability for Lyophilized Leucovorin Calcium Injection	CDER	Bigmar, Inc.	97P-0303 CP 2	11/26/97	01/27/98	
Remove from the market ULTRAM/ TRAMADOL	CDER	Barbara A. Dolan	97P-0494 CP 1	11/26/97	05/27/98	
ANDA for silver sulfadiazine 1% lotion packaged in HDPE plastic	CDER	Sage Pharmaceuticals, Inc.	97P-0493 CP 1	11/28/97	01/27/98	
Amend Regulation for Food and Drugs with Sulfiting Agents	CFSAN/CDER	Center for Science in the Public Interest	82P-0343 CP 1	11/01/82	05/02/83	10/20/83
Establish Definition for Raw Milk and amend Standards of Identity for Milk, Lowfat Milk and Skim Milk	CFSAN	National Milk Producers	84P-0323 CP 1	09/13/84	03/12/85	04/01/97
Canned Shrimp Size Amount Labeling	CFSAN	Am Shrimp Processors Assn.	85P-0456 CP 1	09/20/85	04/04/86	04/04/86
Amend/Revoke Standard of Identity for Can Green Beans	CFSAN	Continental Can Co. Inc.	85P-0503 CP 1	10/23/85	03/24/86	03/24/86
Saccharin in Carbonated Soft Drink for Dietary Use	CFSAN	Nat Soft Drink Assn.	85P-0577/CP 1	12/18/85	06/17/86	09/18/86

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Amend Standard of Identity for Pacific Salmon	CFSAN	Hormel & Co.	86P-0162/CP 1	04/10/86	10/07/86	
Prior Sanction for Special Dietary Uses of Saccharin	CFSAN	Calorie Control Council	86P-0183/CP 1	04/22/86	10/20/86	10/16/86
Amend Standard of Identity for Canned Spinach	CFSAN	Continental Can Co.	86P-0503/CP 1	12/15/86	06/15/87	
Issue Regulation Recogizing a Prior Sanction for Use of Butylated Hydroxyanisole (BHA)	CFSAN	Roger D. Middlekauff, Esq. McKenna, Conner & Cuneo	87P-0057/CP 1	02/20/87	08/20/87	08/13/87
Interpret/Clarify Chap II Sec 201(m) & Chap IV Sec 403(e) & (i) of Act	CFSAN	Betz Labs.	87P-0122/CP 1	04/02/87	09/29/87	
Uniformity of Warning Statements for Food Products	CFSAN	Nat Food Processors Assn.	87P-0140/CP 1	04/20/87	10/19/87	01/06/89
Vinyl Chloride Polymers	CFSAN	Public Citizen/Health Research Group	84N-0334/CP 1	06/30/87	12/28/87	
Uniformity/Consistency in Warning Statement for Cosmetics	CFSAN	CTFA	87P-0264/CP 1	07/31/87	01/27/88	01/06/89
Amend Regulations of Cosmetic Product Labeling	CFSAN	CTFA	88P-0029/CP 1	01/25/88	07/25/88	08/29/88
Label Statement to Include Food Fiber in Dairy Products	CFSAN	Mendenhall Labs.	88P-0284/CP 1	07/29/88	01/26/89	
Amend Standard of Identity for Canned Pacific Salmon	CFSAN	National Food Processors Assn.	88P-0190 CP 2	06/13/89	12/13/89	
Amend Soft Drink Labeling Regulation	CFSAN	National Soft Drink Assn.	89P-0221/CP 1	07/07/89	01/03/90	11/30/89
FD&C Red #3 to Color Additive Advisory Committee for Review	CFSAN	Certified Color Manufacturers Assn., Inc.	90P-0092/CP 1	03/05/90	09/04/90	
FD&C Red #3 to Color Additive Advisory Committee for Review	CFSAN	Cosmetic, Toiletry & Fragrance Association	90P-0092/CP 2	03/05/90	09/04/90	
Labeling of aerosol packages of food & cosmetic products	CFSAN	National Conference on Weights & Measures	90P-0180/CP 1	05/11/90	11/08/90	
Common or Usual Names for Extra Virgin Olive Oil, et al	CFSAN	American Olive Oil Association	90P-0277/CP 1	08/17/90	02/13/91	03/22/91
Peanut Butter Safety	CFSAN	The American Peanut Butter Project	90P-0395/CP 1	11/08/90	05/07/91	
Prohibit the Term "Fresh" on Labels of Processed Tomato Products	CFSAN	California Tomato Packers	90P-0430/CP 1	12/07/90	06/05/91	
Standard of Identity for Ultrapasteurized Egg Products	CFSAN	Michael Foods, Inc.	91P-0050/CP 1	02/13/91	08/13/91	07/31/91

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Adopt a Regulation to Codify the Name "Cooking Wine"	CFSAN	Monarch Wine Company of Georgia, et al	91P-0051/CP 1	02/13/91	08/13/91	
Amend Regulations for Food Labeling Print Size	CFSAN	Lois M. Meyer	91P-0234 CP 1	06/24/91	12/23/91	
Standard of identity for canned fruit cocktail	CFSAN	Sierra Quality Canners	91P-0236 CP 1	06/25/91	12/23/91	
Request for Exemption from Special Requirements for Labeling	CFSAN	Nutrients Incorporated	91P-0297 CP 1	07/17/91	01/27/92	
Amend Standards for Identity Regs. for Dried Eggs/Egg Yolks	CFSAN	J. M. Huber Corporation	91P-0417 CP 1	10/16/91	04/13/92	04/08/92
Amend Regulation Regarding Designation of Ingredients	CFSAN	CTFA	91P-0446 CP 1	10/30/91	04/28/92	
Establish Standard for Coffee Labeled "Kona Coffee"	CFSAN	Kona Coffee Council	91P-0510 CP 1	12/23/91	06/22/92	07/10/92
Advisory Opinion Regarding Official Recognition of Updated Food Chemicals Codex	CFSAN	Hercules Inc.	92A-0052 AP 1	01/30/92	07/28/92	
Safety Standard for Alcohol based Hairsprays	CFSAN	Cosmosol Ltd.	92P-0062 CP 1	02/07/92	08/04/92	09/21/92
Amend Regulations Pertaining to Calcium & Vitamin D	CFSAN	Rutgers	92P-0064 CP 1	02/07/92	08/04/92	11/05/93
Set limit for Methylmercury in Seafood	CFSAN	Public Voice for Food & Health Policy	92P-0170 CP 1	04/07/92	10/05/92	
Exemption from Preemption for California Bottled Water Standards	CFSAN	California Department of Health Services	92P-0216 CP 1	05/14/92	11/09/92	
Premarket Testing, Labeling of Genetically Engineered Foods	CFSAN	The Foundation on Economic Trends	92P-0222 CP 1	05/19/92	11/16/92	05/17/94 Partial
Amend the Use of Aluminum Sulfate, etc in Food	CFSAN	Glen Scott, M.D.	92P-0246 CP 1	06/05/92	12/02/92	
Clarify Schedule for Submission & Agency's response Re: FAP	CFSAN	McNeil Specialty Products Co.	92P-0268 CP 1	06/22/92	12/21/92	
Exemption from FDA Regulations for Slack Fill	CFSAN	State of California, Dept. of Justice	92P-0361 CP 1	09/11/92	08/10/92	
Public Health Message on Food Labels & Labeling	CFSAN	Nat. Institute Science, Law & Public Policy	85N-0061 PRC 1	02/08/93	08/09/93	
Exempt Infant Formulas from Size Requirements	CFSAN	Infant Formula Council	93P-0070 CP 1	02/17/93	08/17/93	10/01/93
Amend Guide CPG 7101.04 (Dealcoholized Wine Labeling)	CFSAN	Private Cellers, Ltd.	93P-0098 CP 1	03/05/93	09/01/93	

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Affirm the GRAS Status of Sodium Thiosulfate as Reducing Agent in Brewed Coffee and Tea	CFSAN	Selecto, Inc.	93P-0103 CP 1	03/09/93	09/07/93	01/27/94
Prohibit misbranding of whole wheat products	CFSAN	Center for Science in the Public Interest	93P-0227 CP 1	06/25/93	12/22/93	01/14/94
Amend Regs. re: Placement of Soft Drink Identity Statements	CFSAN	National Soft Drink Assn.	93P-0296 CP 1	08/05/93	02/01/94	
Amend Food Labeling Requirements to Exempt Infant Formulas	CFSAN	MeadJohnson Nutritionals, U.S.	93P-0302 CP 1	08/11/93	03/09/94	
Amend Nutrient Labels not a Significant source Statement	CFSAN	Wine Institute	93P-0486 CP 1	12/21/93	06/20/94	
Health Claims for Antioxidant Vitamins and Cancer	CFSAN	American Preventive Medical Assn.	93N-480A PSA 1	01/21/94	07/25/94	
Health Claims for Dietary Fiber and CVD	CFSAN	American Preventive Medical Assn.	93N-480C PSA 1	01/21/94	07/25/94	
Health Claims for Dietary Fiber and Cancer	CFSAN	American Preventive Medical Assn	93N-480F PSA 1	01/21/94	07/25/94	
Health Claims; Omega-3 Fatty Acids and CHD	CFSAN	American Preventive Medical Assn.	93N-480O PSA 1	01/21/94	07/25/94	
Health Claims for Zinc & Immune Deficiency in Elderly	CFSAN	American Preventive Medical Assn.	93N-480Z PSA 1	01/21/94	07/25/94	
Health Claims & Label Statements Folate & NTD's	CFSAN	American Preventive Medical Assn. et al	93N-0481 PSA 1	01/31/94	08/03/94	
Require Statement 'Not a Significant Source of _____'	CFSAN	Calorie Control Council	94P-0029 CP 1	02/03/94	08/02/94	
Food Labeling; General Requirements for Health Claims for Dietary Supplements	CFSAN	National Council for Improved Health	85N-061D PSA 1	02/07/94	08/08/94	
Food Labeling; General Requirements for Nutrition Labeling for Dietary Supplements	CFSAN	National Council for Improved Health	90N-135D PSA 1	02/07/94	08/08/94	
Food Labeling; General Requirements for Nutrient Content Claims	CFSAN	National Council for Improved Health	91N-384D PSA 1	02/07/94	08/08/94	
Dietary Supplements; Establishment of Date of Application	CFSAN	National Council for Improved Health	93N-0478 PSA 1	02/07/94	08/08/94	
Health Claims & Label Statements; Folate & NTD's	CFSAN	National Council for Improved Health	93N-0481 PSA 2	02/07/94	08/08/94	
Health Claims for Antioxidant Vitamins & Cancer	CFSAN	National Council for Improved Health	93N-480A PSA 2	02/07/94	08/08/94	
Health Claims for Dietary Fiber & CVD	CFSAN	National Council for Improved Health	93N-480C PSA 2	02/07/94	08/08/94	
Health Claims for Dietary Fiber & Cancer	CFSAN	National Council for Improved Health	93N-480F PSA 2	02/07/94	08/08/94	
Health Claims; Omega-3 Fatty Acids and CHD	CFSAN	National Council for Improved Health	93N-480O PSA 2	02/07/94	08/08/94	
Health Claims for Zinc & Immune Deficiency in Elderly	CFSAN	National Council for Improved Health	93N-480Z PSA 2	02/07/94	08/08/94	

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Require Labeling of Trans Fatty Acid & Prohibit Deceptive Claims	CFSAN	Center for Science in the Public Interest	94P-0036 CP 1	02/14/94	08/15/94	03/03/95
Establish Common or Usual Name for Blue Crab	CFSAN	National Blue Crab Industry Association	94P-0043 CP 1	02/18/94	08/17/94	
Clarify use of Simplified Nutritional Labeling Format	CFSAN	National Soft Drink Assn.	94P-0079 CP 1	03/09/94	09/06/94	09/27/94
Modify Ingredient Label for In-Store Prepared Take-Out food	CFSAN	Food Marketing Institute & National Grocers Association	94P-0187 CP 1	05/20/94	11/16/94	
Establish Common or Usual Name for Peanut Butter Spread	CFSAN	Hunt-Wesson, Inc. & CPC International Inc.	94P-0190 CP 1	05/23/94	11/21/94	12/06/94
Amend Portions of the Canned Tuna Standard of Identity	CFSAN	United States Tuna Foundation	94P-0286 CP 1	07/28/94	01/24/95	03/30/95
Issue Regulations to Provide Consistency in Use of Term "sugar"	CFSAN	The Sugar Association Inc	94P-0293 CP 1	08/03/94	01/31/95	02/02/95
Amend Standard of Identity for Enriched Macaroni & Noodle Products	CFSAN	National Pasta Assn & Millers' National Federation	94P-0413 CP 1	11/15/94	05/15/95	06/05/95
Seeking Carcinogenic Labeling on all Cosmetic Talc Products	CFSAN	Cancer Prevention Coalition	94P-0420 CP 1	11/22/94	05/22/95	04/01/96
Amend Food Additive Petition Form	CFSAN	Calorie Control Council	95P-0044 CP 1	02/16/95	08/15/95	09/18/95
Permit the Removal of Fat from Standardized Foods	CFSAN	Calorie Control Council	95P-0078 CP 1	03/13/95	09/11/95	09/27/95
Permit term Polyols in Lieu of Sugar Alcohols on Food Label	CFSAN	Calorie Control Council	95P-0099 CP 1	04/13/95	10/16/95	11/07/95
Hot Dogs Contain Nitrites-Label with Cancer Risk (Warning)	CFSAN	Cancer Prevention Coalition	95P-0112 CP 1	05/03/95	10/30/95	
Regulatory Action to Prohibit Misleading Food Labeling	CFSAN/COMM	Center for Science in the Public Interest	95P-0246 CP 1	08/02/95	02/01/96	
Fortification of Foods with Vitamin B6	CFSAN	John Marion Ellis, MD	95P-0392 CP 1	12/06/95	06/04/96	06/17/97
Monograph on Potassium Chloride as GRASP	CFSAN	Kaliu, Canada, Ltd.	96P-0016 CP 1	01/18/96	07/21/96	07/10/96
Revoke Provisions of Standard of Identity for Yogurt	CFSAN	National Yougurt Association	96P-0073 CP 1	03/01/96	08/31/96	10/21/96
To accurately communicate scientific fact about stearic acid	CFSAN	American Cocoa Research	96P-0111 CP 1	04/04/96	10/01/96	03/24/97
Amend the Food Labeling Regulations to permit removal or reduction of an ingredient specially required by standard of identify	CFSAN	Calorie Control Council	96P-0143 CP 1	05/03/96	10/30/96	11/01/96

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Change FDA Food Labels show exact percentage of calories	CFSAN	Americans For Truth in Labeling Committee	96P-0211 CP 1	06/26/96	12/24/96	06/03/97
Grant exception for Label Declaration of ingredients for Black Olives	CFSAN	Purac America, Inc.	96P-0230 CP 1	07/02/96	12/29/96	12/24/96
Regulations re: false and/or misleading use of "organic"	CFSAN	Aubrey Organics, Incs	96P-0267 CP 1	07/25/96	01/26/97	
International Cosmetic Ingredient Dictionary - Harmonization	CFSAN	CTFA	96P-0347 CP 1	09/20/96	03/24/97	07/07/97
Req minimum 25microgms crystalline vitamin B12 fortification	CFSAN	Victor Herbert MD JD	96P-0349 CP 1	09/26/96	03/25/97	06/16/97
Cosmetics containing diethanol-amine, warning labels	CFSAN	Cancer Prevention Coalition etc	96P-0404 CP 1	10/24/96	04/22/97	
Reduce the Precense of Salmonella Enteritidis in Shell Eggs	CFSAN	Rose Acre Farms, Inc.	96P-0418 CP 1	11/04/96	05/04/97	05/05/97
Prevent Unapproved Use of the Term "Energy" on Food Labels	CFSAN	Center for Science in the Public Interest	96P-0464 CP 1	12/03/96	06/01/97	06/02/97
Presence of Lead in Certain Dietary Calcium Supp & Antacids	CFSAN	Natural Resources Defense Council, et al	97P-0034 CP 1	01/27/97	07/26/97	07/25/97
Definitions & Standards of Identity for Bakery Products	CFSAN	American Bakers Assoc.	97P-0043 CP 1	02/04/97	08/03/97	
Caloric value not more than two per gram for soluble fiber	CFSAN	Calorie Control Council	97P-0056 CP 1	02/13/97	08/12/97	08/08/97
Hair defects in imported canned Mushroom	CFSAN	International Trade Group LLC	97P-0057 CP 1	02/12/97	08/13/97	
Recognized the Term "Soymilk" as the Established Common of Usual Name	CFSAN	Soyfoods Association of America	97P-0078 CP 1	02/28/97	08/30/97	08/04/97
Require Percentage Ingredient Labeling	CFSAN COMM	Center for Science in the Public Interest	97P-0130 CP 1	04/01/97	09/28/97	10/29/97
Repeal standards of identity for artificially sweetened jam	CFSAN	International Jelly & Preserve Association	97P-0142 CP 1	04/07/97	10/05/97	
Amend the Definition of 'total fat' & 'saturated fat'	CFSAN	Nabisco Inc.	97P-0187 CP 1	05/08/97	11/08/97	11/13/97
Require warning labels about risks of salmonella enteritis	CFSAN	CSPI	97P-0197 CP 1	05/14/97	11/11/97	
Yellow prussiate of soda anticaking agent potassium	CFSAN COMM	Morton International	97P-0229 CP 1	06/09/97	12/07/97	
Maintain current system establishing lead limits food	CFSAN CDER/COMM	Council for Responsible Nutrition & NDMA	97P-0233 CP 1	06/11/97	12/08/97	12/05/97

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
CP Regarding soluble fiber from whole oats & Coronary Disease	CFSAN COMM	American Association of Cereal Chemists	97P-0306 CP 1	07/18/97	01/14/98	
Require Quantitative Labeling of Caffeine Content	CFSAN COMM	CSPI	97P-0329 CP 1	08/01/97	01/28/98	01/29/98
Expiration Date Labeling of Food Products	CFSAN	Lt. Colonel John J. Lighter	97P-0360 CP 1	08/19/97	02/17/98	
Require Complete Mailing Address on all Packaged Food Products	CFSAN	Lt. Colonel John J. Lighter	97P-0361 CP 1	08/19/97	02/17/98	
Investigations operations manual guideline/comp standards	CFSAN	Cocoa Merchants Assocation of America	97P-0407 CP 1	09/23/97	03/22/98	
Amend type size exemptions-labels including nutrition information	CFSAN	Wakunaga Co., Ltd.	94P-0110 PRC 1	10/23/97	04/22/98	
Amend type size exemptions-labels including nutrition information	CFSAN	American Herbal Products. Association	94P-0110 PRC 2	10/23/97	04/22/98	
Amend type size exemptions-labels including nutrition information	CFSAN	Council for Responsible Nutrition	94P-0110 PRC 3	10/23/97	04/22/98	
Amend type size exemptions-labels including nutrition info.	CFSAN	American Herbal Products Association	94P-0110 PRC 4	11/24/97	05/24/97	
Statement of Identity, Nutrition Labeling and Ingredient	CFSAN	Wakunaga Co., Ltd.	95N-0245 PRC 1	10/23/97	04/22/98	
Statement of Identity, Nutrition Labeling and Ingredient	CFSAN	American Herbal Products. Association	95N-0245 PRC 2	10/23/97	04/22/98	
Statement of Identity, Nutrition Labeling and Ingredient	CFSAN	Council for Responsible Nutrition	95N-0245 PRC 3	10/23/97	04/22/98	
Statement of Identity, Nutrition Labeling and Ingredient	CFSAN	American Herbal Products Association	95N-0245 PRC 4	11/24/97	05/24/98	
Whooping Cough Vaccine	CBER	Theresa M. Pandullo	85P-0171 CP 1	04/05/85	10/01/85	
FDA to Delete 21 CFR 606.151 Compatibility Testing	CBER	W M Beaumont Hospital Clinical Pathology	86P-0102 CP 1	02/28/86	09/24/86	
Poliovirus Vaccine Live Oral; Additional Standards	CBER	Lederle Laboratories	86N-0027 PSA 1	06/07/91	12/09/91	
Resolve Potential Threat-Vaccines, Viruses, AIDS, etc.	CBER	Foundation on Economic Trends	87P-0259 CP 2	06/10/91	12/09/91	
Refrain from action against Genetic Systems HIV-1 test kits	CBER/CDRH	Bourget Health Services, Inc.	92P-0250 CP 1	06/12/92	12/09/92	08/06/92
Request to Deregulate assays by Clinical Labs for In-Home Assays	CBER	Hyman, Phelps & McNamara, P.C.	92P-0405 CP 1	10/23/92	04/26/93	

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Add Terminal Dry-Heat Inactivation of Plasma-Derived Factor8	CBER	Columbia University School of Public Health	95P-0378 CP 1	11/20/95	05/25/96	03/15/96
Regulate Blood Establishment Software Programs	CBER	Akin, Gum, Strauss, Hauer & Feld	96P-0087 PSA 1	03/07/96	09/07/96	09/03/96
Draft Doc. Concerning the Reg. of Placental/umbilical Cord Blood	CBER	Morgan, Lewis & Bockius	96N-0002 PSA 1	06/06/96	12/08/96	11/19/96
Sale of Home Test Kits for HIV in Wyoming, Advisory Opinion	CBER	Department of Health, State of Wyoming	96A-0331 AP 1	09/09/96	03/16/97	
Rotating Membrane Filtration Blood Cell Separtion Systems	CBER	Baxter Healthcare Corporation	96P-0484 CCP 1	12/11/96	06/10/97	06/03/97
Software Developed by Blood Cts is not subject to device	CBER/COMM CDRH	Association of Independent Blood Centers	97P-0039 CP 1	01/28/97	07/28/97	
PSA/standardization of certain grass pollen extracts	CBER	Allergen Products Mfg. Assoc	97P-0281 CP 1	07/01/97	12/29/97	12/23/97
PSA/standardization of certain grass pollen extracts	CBER	Allergen Products Mfg. Assoc	97P-0281 PSA 1	07/01/97	12/29/97	
Biological products are also drugs requiring PHSA & FFDCA	CBER	Foley & Lardner	97P-0373 CP 1	09/04/97	03/03/98	
Implement a Series of Changes in the Regulatory Process for New Animal Drug Products	CVM	American Veterinary Medical Association	91P-0434 CP 1	10/22/91	04/20/92	10/05/92
Permit Vets. to Dispense & Compound Legally Available Drugs	CVM	Hyman, Phelps & McNamara	92P-0409 CP 1	10/28/92	04/26/93	04/20/93
Remove Ethoxyquin from Dog Food Products	CVM	United Animal Owners Association	93P-0081 CP 1	02/09/93	08/09/93	08/11/93
Amend Regulations for Liquid Animal Feed	CVM	American Feed Industry	93P-0174 CP 1	04/30/93	10/29/93	04/19/95
Amend Definition of "Biological Products"	CVM	Animal Health Institute	93P-0337 CP 1	09/16/93	03/15/94	03/14/94
Require NADA for Products used in Freshwater or Marine Aquariums	CVM	Committee on Safe and Effective Aquarium Drugs	93P-0396 CP 1	10/19/93	04/18/94	07/15/94
Regs Designating Certain Life Stages of Fish as Non-food	CVM	Nat. Aquaculture Council div. Nat Fisheries Institute	94P-0291 CP 1	08/03/94	01/31/95	02/01/95
Revoke the use of rBGH, BST and Prosilac	CVM	Robert Cohen	94P-0343 CP 1	09/14/94	03/16/95	02/03/95
Reevaluate Regs. & Policies Regarding Supplemental NADA	CVM	Animal Health Institute	95P-0330 CP 1	10/10/95	04/07/96	08/01/96
Current GMP Regulations for Medical Feeds	CVM	American Feed Industry Association	95P-0373 CP 1	11/13/95	05/12/96	07/30/97
Safe Use of Menadione Nicotinamide Bisulfite	CVM	Heterochemical Corporation	94F-0283 PSA 1	02/05/96	08/04/96	
Cosequin Dietary Supplement	CVM	Luitpold Pharmaceuticals, Inc.	96P-0093 CP 1	03/14/96	09/18/96	10/03/96

PENDING PETITIONS

SUBJECT	AGENCY COMPONENT	SUBMITTER	DOCKET NUMBER/ *PETITION TYPE	DATE RECEIVED	RESPONSE DUE DATE	INTERIM RESPONSE
Prevent Outbreak of Bovine Spongiform Encephalopathy (BSE)	CVM	Internatl. Center for Technology Assessment	96P-0106 CP 1	03/28/96	09/24/96	9/30/96
Prohibit promoting & marketing of CSP for treatment of cats	CVM	Rosemary Jacobs	96P-0455 CP 1	10/09/96	05/24/97	04/10/97
Final Rule Re: Extralabel Drug Use in Animals	CVM	Humane Society of the U.S.	96P-0480 CP 1	12/09/96	07/15/97	07/08/97

Total Pending Petitions: 575

*Type of Petition: VAR (Variance), CP (Citizen Petition), PSA (Petition for Stay of Action), PRC (Petition for Reconsideration), and CCP (Change in Classification Petition). This is also the item code assigned to the petition within the docket.

Send to DPC. Mailing FDA file

November 21, 1997

President Bill Clinton
The White House
1600 Pennsylvania Ave.
Washington, D.C. 20500

RE: FDA streamlining / example of good effect here . . .

Dear President Clinton,

HOWELL DESIGN, INC.
192 Thomas Lane
Stowe, Vermont 05672

My name is Rick Howell and I'm president of Howell Design, Inc., a very small company here in Stowe, Vermont that develops leading breakthrough consumer products---mostly sports products---but we also have developed / manufacture / distribute a medical device called the Reader's Window, which is a patented book holder that props books up at eye level for people who read in reclining chairs and it actually *suspends* books in an inverted position so you can view at "11:00" while reading in bed. Millions of people who have neck, upper back, and arm weakness can now read with full efficiency with this product.

We have received 100% rave reviews from independent editorial critics who have evaluated this medical device, including *The Wall Street Journal* and *Prevention* magazine and it is soon to be favorably reviewed by the *Berkeley Wellness Newsletter*, and *Health* magazine and others. Noted medical researcher, Malcolm H. Pope, Dr. Medical Science, PhD Engineering, Professor of Biomedical Engineering and Director of the Spinal Research Center at the U. of Iowa has gone on the record to praise this breakthrough new way to read that can help so many average citizens.

However, we have purposely avoided applying for FDA approval due to the convoluted and expensive process at the FDA.

Now, based on the signing of your new FDA Act, today, streamlining the FDA, we will go for FDA approval. Based on the many M.D.'s who already support us, we know that we will now gain approval---and hopefully---we will do so efficiently. FDA approval will increase the credibility of the device, causing millions of people to benefit, reducing long term health care costs because neck/back/arm strain will be lessened. This, in turn, will create more jobs not only here in Stowe, Vermont, but nationally at the 100+ *Relax the Back* retail stores that sell the device.

If I can be of example to you on how this may help us and therefore help a wide range of people and the economy, please advise. Maybe our company could be a test to see how well it goes?

Sincerely,
Howell Design, Inc.

Richard Howell, President

phone 802-253-4458
800-867-7869
fax 802-253-8817

FDA

Food and Drug Administration – FY 2000 Budget Request

FDA's FY 2000 budget request includes funding to improve product safety assurance (including inspectional coverage) and continued funding for the Food Safety Initiative (which also includes inspections, though different from that listed above).

Product Safety Assurance -- ($ 126.1 million, 316 FTE)

Problem Identification: FDA's ability to inspect domestic and imported products has fallen considerably over the past few years, even as consumer expectations continue to rise with regard to our regulatory presence hindering achievement of these objectives. Since the early 1980's, the number of food establishment inspections conducted by FDA has declined from over 21,000 to the current level of approximately 5,600 inspections per year. Consequently, we now inspect domestic establishments on an average of once every seven years, including inspections carried out under contract by the states. With regard to imported food products, since FY 1991 the number of entries has increased from 1.1 million per year to 2.1 million per year in FY 1997. FDA's level of coverage for imported foods has declined from 7.6 percent in 1993 to the current level of 1.6 percent in 1997. We are somewhat more successful in our inspection rates for pharmaceutical and device manufacturers (about once every three years), but still short of statutory requirements.

Goal: Inspect manufacturing facilities a minimum of once every two years, in accordance with statutory requirements.

FDA's Proposed Response: In considering how to effect a proper and effective inspection program in the 21st century, FDA is looking to discontinue traditional approaches that have served the public well through nine decades, but that will not be adequate as we move into the next millennium. FDA must refocus its efforts both internally and externally -- internally we must strengthen the roles of standard setting and oversight, and externally we must become teachers and auditors.

FDA must maintain a highly skilled, flexible workforce, fully capable of understanding and applying the science of the day in order to promulgate regulations appropriate to industry, and pass judgment on products submitted for approval. But FDA must go beyond this and impart that knowledge to others who will use it to supplement our efforts and help assure the overall safety of products supplied to the American public and the world at large. Coupled with this research and regulation, there must be a strong, capable oversight arm to ensure safety, honesty, and fair dealing.

Traditionally, we have held that FDA was better, faster, and smarter than any other body, with regard to consumer protection. However, given the growth of consumer protection responsibilities and changing characteristics of society, it is apparent that FDA cannot do everything itself. While it is critical that the Agency have the resources necessary to fulfill our mandates, it is equally important that we look to other regulatory bodies and the industry itself to shoulder part of the responsibility for providing safe and effective products

to the market. We propose substantial investments to be made through state contracts, augmented by increases in FDA training programs to provide the tools necessary to achieve our goals of meeting all statutory inspection obligations and to increase the frequency of inspection on all commodities regulated by FDA.

We are seeking funding to achieve our goal of meeting statutory timeframes for inspections. For drugs, biologics, animal drugs, and medical devices, this would be inspecting each manufacturer every two years, and for warehouse facilities this means an inspection once every four years. Funding would also allow the Agency to focus on technical assistance to enhance industry compliance, integrate public health regulation with the states through contracts, partnerships, training, and information sharing, and maintain the integrity of data supporting import entry decisions. Resources would also be used to provide for foreign inspections and evaluations, as well as provide technical assistance to foreign countries.

Breaking from our traditional approach, this funding would *not* be used to hire thousands of additional FDA inspectors, but instead, would leverage the enormous potential of partnering with the states, and establish a national database of inspections that would be available to local, state, and Federal health officials, thereby eliminating duplication of effort and substantially increasing inspectional coverage.

Specifically, funding would be used to: increase the number of import food samples analyzed; review a higher proportion of imports that are offered for entry; address the issue of drug mail entries such as for personal importation; and enhance data systems (the existing OASIS and the new International Trade Data System -- ITDS) to permit profiling and trend analysis of imports. Funding would also be used to buy nearly 19,000 additional inspections through contracts with the states. With the increased resources, FDA will be able to inspect food manufacturing facilities a minimum of once every four years, and high-risk food establishments once a year. Funding at this level would also cover the increased costs of operations under the Office of Criminal Investigations, and provide for the research critical to target efforts on those areas with the most potential for dangerous injuries, as well as develop better methods for testing and analysis necessary to support these initiatives.

This request also includes $50.3 million for construction of critically needed facilities in support of FDA's goal of improving public health infrastructure. This funding would provide sufficient resources to build a desperately needed replacement laboratory facility in Los Angeles ($40.4 million), and complete Phase III of the Arkansas Regional Laboratory ($9.9 million) facility.

The table below summarizes the request for Product Safety Assurance by program and activity area:

FY 2000 Funding Request -- Product Safety Assurance
(Dollars in Millions)

Program	Request
Foods	$29.0
Human Drugs	$13.2
Biologics	$6.2
Animal Drugs & Feeds	$4.8
Devices	$17.9
Other Activities	$4.7
Buildings & Facilities	$50.3
Total	$126.1

Food Safety Initiative (FSI) -- ($ 48.9 million, 152 FTE)

Problem Identification: Foodborne illness continues to be a problem that affects millions of consumers every year. Current data indicate that annually from 6.5 to 33 million Americans become ill from foodborne contaminants such as microbial pathogens. The FSI, emphasizes interagency coordination, more comprehensive and accurate data on the number and causes of foodborne illnesses, faster and more accurate analytical methods for detecting microbial pathogens and mycotoxins, more effective techniques for assessing the risk associated with foodborne contaminants, and the development of more effective strategies for educating industry and consumers on proper food handling procedures. FDA and its federal and state partners will be able to provide greater protection for consumers by responding more rapidly to food safety emergencies, and by more efficiently and effectively using available resources to prevent foodborne hazards.

Goal: Reduce the incidence of deaths and diseases resulting from foodborne pathogen contaminants.

FDA Proposed Response: In FY 2000, the Foods Program will increase its outbreak response work, tracing back through the food distribution and production chain to find the source of contamination that caused an outbreak. This work will increase as the FoodNet system matures and the data becomes more reliable in FY 2000. We will continue to focus on antimicrobial resistance. The identification and containment of resistance as a result of the monitoring programs will help ensure the continued effectiveness of both human and veterinary drugs, and aid in increasing the availability and distribution of effective drugs. Food production preventive controls systems work will increase, including development of additional industry guidance and HACCP where appropriate.

Available data indicates that foods prepared by retail food service are the source of a large number of outbreaks. Most retail food service outlets are regulated by the states. Accordingly, the Agency will work with states to achieve adoption of the Food Code by states, develop performance standards for food service workers, and provide education and training to support Food Code adoption and change unsafe behaviors. With a goal of developing a vertically integrated national food inspection system, resources will be devoted to provide state inspectors with resources and training, where needed, to conduct inspections that are complementary to FDA inspections and ultimately, provide a nationwide, uniformly applied food safety system. Inspections on high-risk areas (such as seafood) will be conducted once per year. Work in the area of imported foods will expand to cover additional products or practices. Work will also continue in the major areas to address the food safety issues identified in the original Food Safety Initiative and the more recently developed Fresh Produce Initiative. These areas include surveillance, coordination, inspections and compliance, education, research, and risk assessment. Again, research and risk assessment, which provides a cornerstone for targeting scarce resources to those areas that yield the most benefits, will continue to support these activities.

FY 2000 Funding Request -- Food Safety Initiative
Dollars in Millions

Program	Request
Foods	$40.8
Animal Drugs and Feeds	$6.1
NCTR	$1.0
Other Activities	$1.0
Total	$48.9

FDA - MS

FDA Success Stories in Clinton Administration

- Tobacco
- Drug Approval
- Food Safety/Seafood HACCP
- Biotechnology
- AIDS (drugs, blood, test kits, vaccines)
- REGO
- Pediatric Labeling
- Mammography
- High Profile Food Additives (BST, Olestra, Sucralose, Meat Irradiation)
- BSE

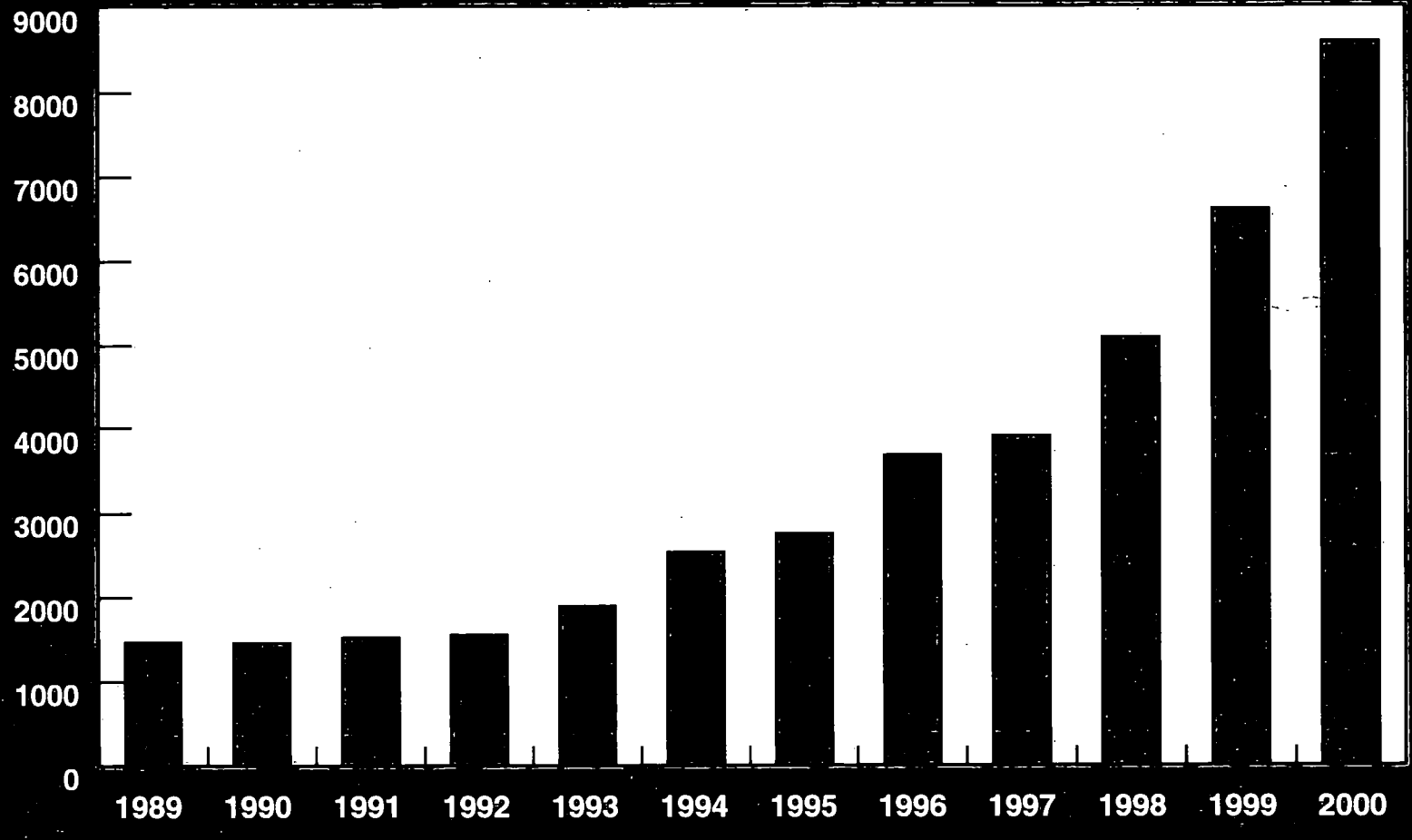
Crushing New Responsibilities

- Soaring Workload Increases for each of last 5 years
  - 12% Annual Increase in Product Applications
  - 24% Annual Increase in Imports
  - 25% Annual Increase in Injury Reports
  - 5% Annual Increase in Regulated Firms
- Complex New Products/Technologies
  - Genetic Testing
  - Gene Therapy
  - Tissue Transplantation (Human and Xeno)
  - Cloning
  - Anti-Viral Drugs
  - Computerized Devices/Manufacturing Processes
  - Novel Foods
  - Biotechnology

Crushing New Responsibilities

- New Challenges
  - Blood Safety
  - New Diseases (AIDS, BSE, HUS, CJD)
  - Emerging Pathogens
  - Counterfeiting
  - Tampering
  - Dietary Supplements
  - Drug Promotion in Managed Care/On Internet
  - International Harmonization
  - Home Test Kits
- New Statutory Responsibilities
  - 10 Major New Laws Since 1990
- FDA Modernization Act
  - 100 new regs, guidances, etc.
- Presidential Initiatives
  - Tobacco
  - Food Safety
  - REGO
  - Bioterrorism

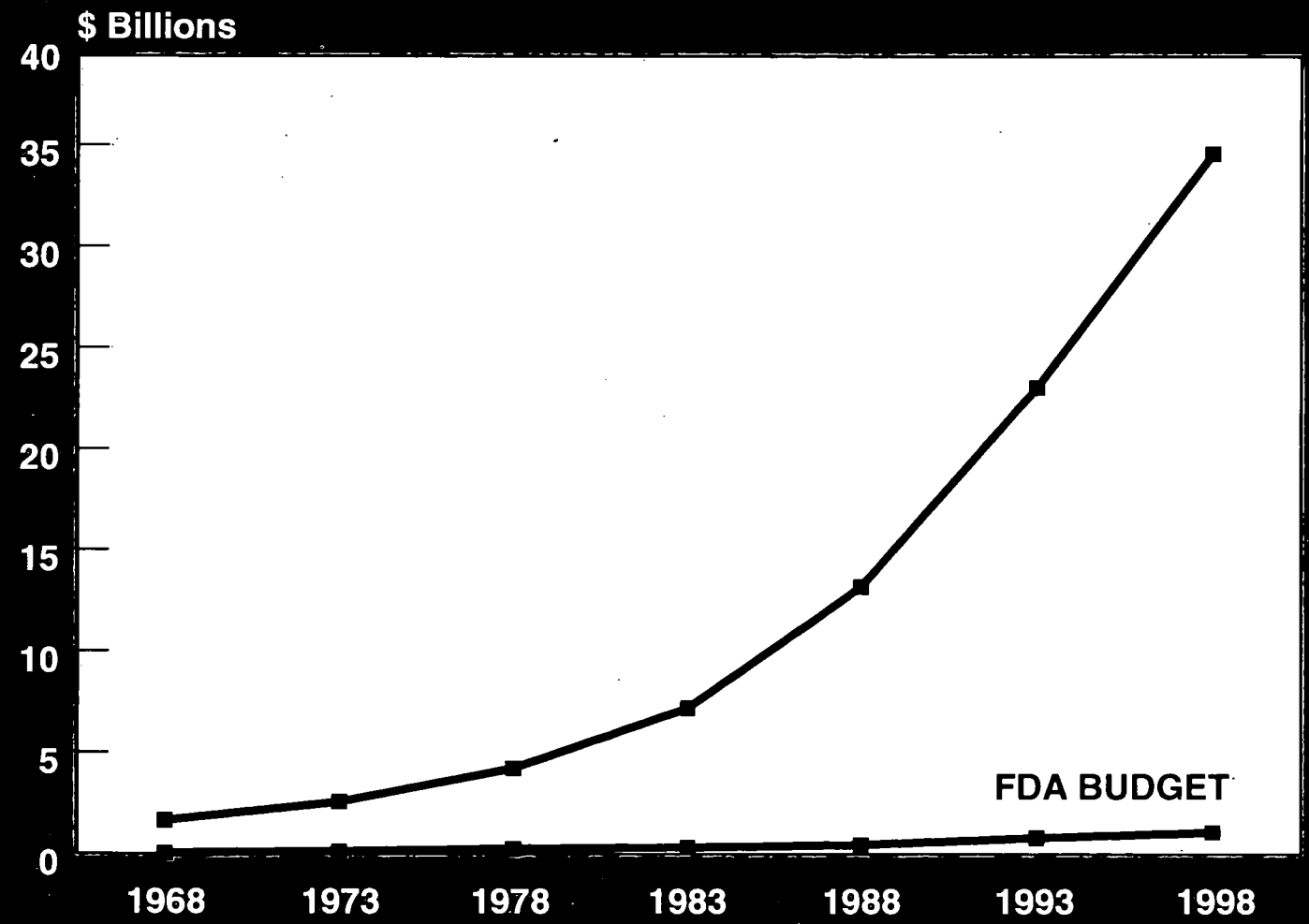
FDA Import Entries



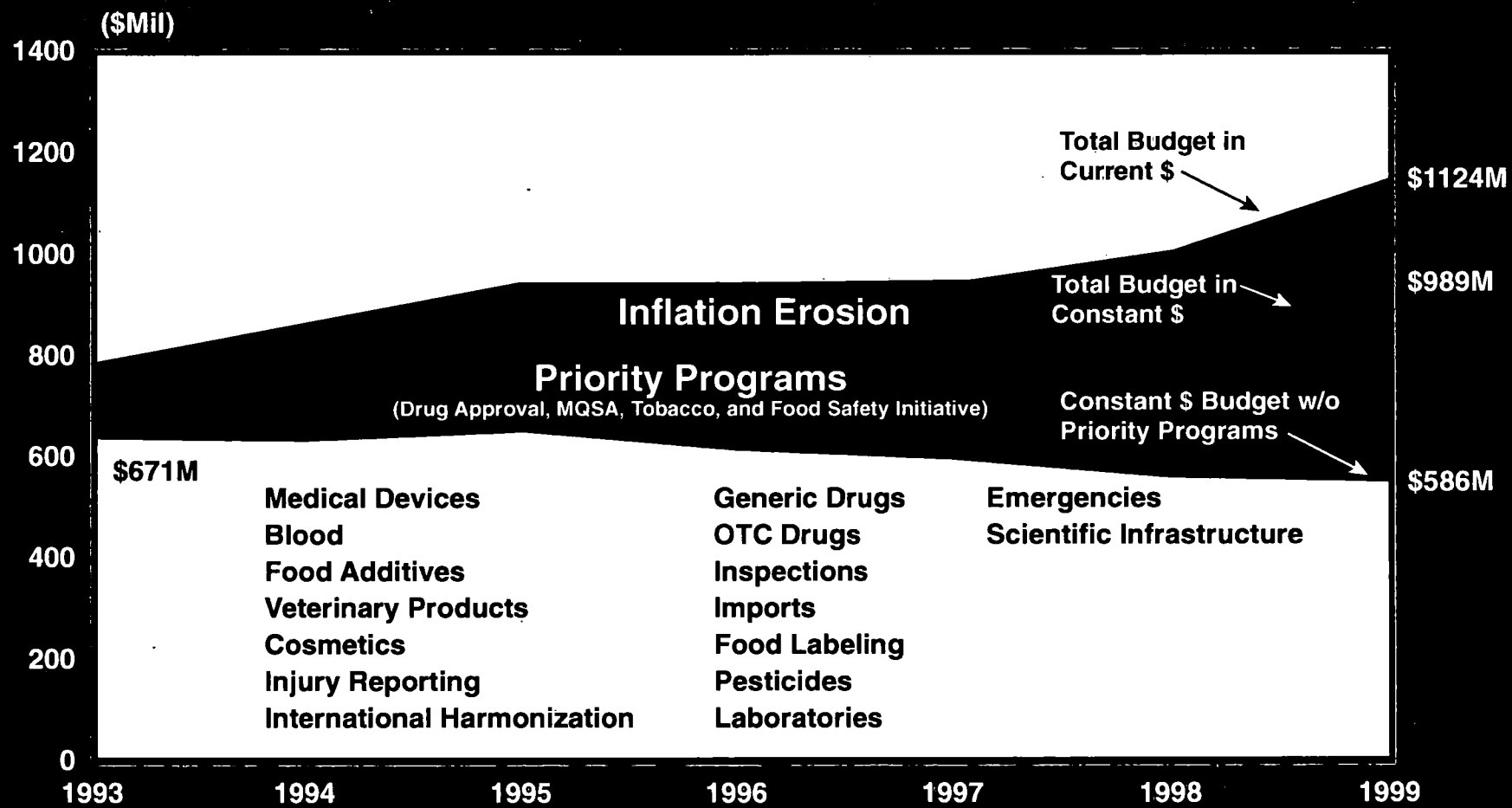
Note: The numbers for the years 1998, 1999 and 2000 are projected

US Biomedical R&D Expenditures

Public (NIH) + Private (PhRMA)



The Shrinking FDA



What Does This Mean?

- Failure of Import Program
  - Will inspect less than 1% by 2000
- Inspections at Historically Low Levels
  - General food inspections (filth) no longer done
  - Food inspections down to 5,000 (vs. 21,000 in 1981)
  - Only 10% of foreign drug firms inspected annually
  - Only 50% of highest risk device manufacturers inspected within statutory interval (virtually no low risk)
  - Only 33% of veterinary drug manufacturers inspected within statutory interval
  - Tissue and organ banks rarely inspected
- Product Recalls Doubled in Recent Years

FDA

What Does This Mean?

- Many Products Virtually Unregulated
  - Dietary supplements
  - Cosmetics
  - Medical products purchased overseas
  - Elimination of foreign pesticide monitoring/phase out of U.S. field sampling
- Health fraud and economic fraud enforced only for outrageous violations
- New products/technologies slowed to market
- Adverse event reports 250,000/year and increasing
- Citizen petition backlog of 600 petitions

OMB

EPA

Commerce

DOE

- USDA
- FDA
- DOT

What Can Be Done?

Focus FY 2000 Budget Priorities to Strengthen Four Critical Areas

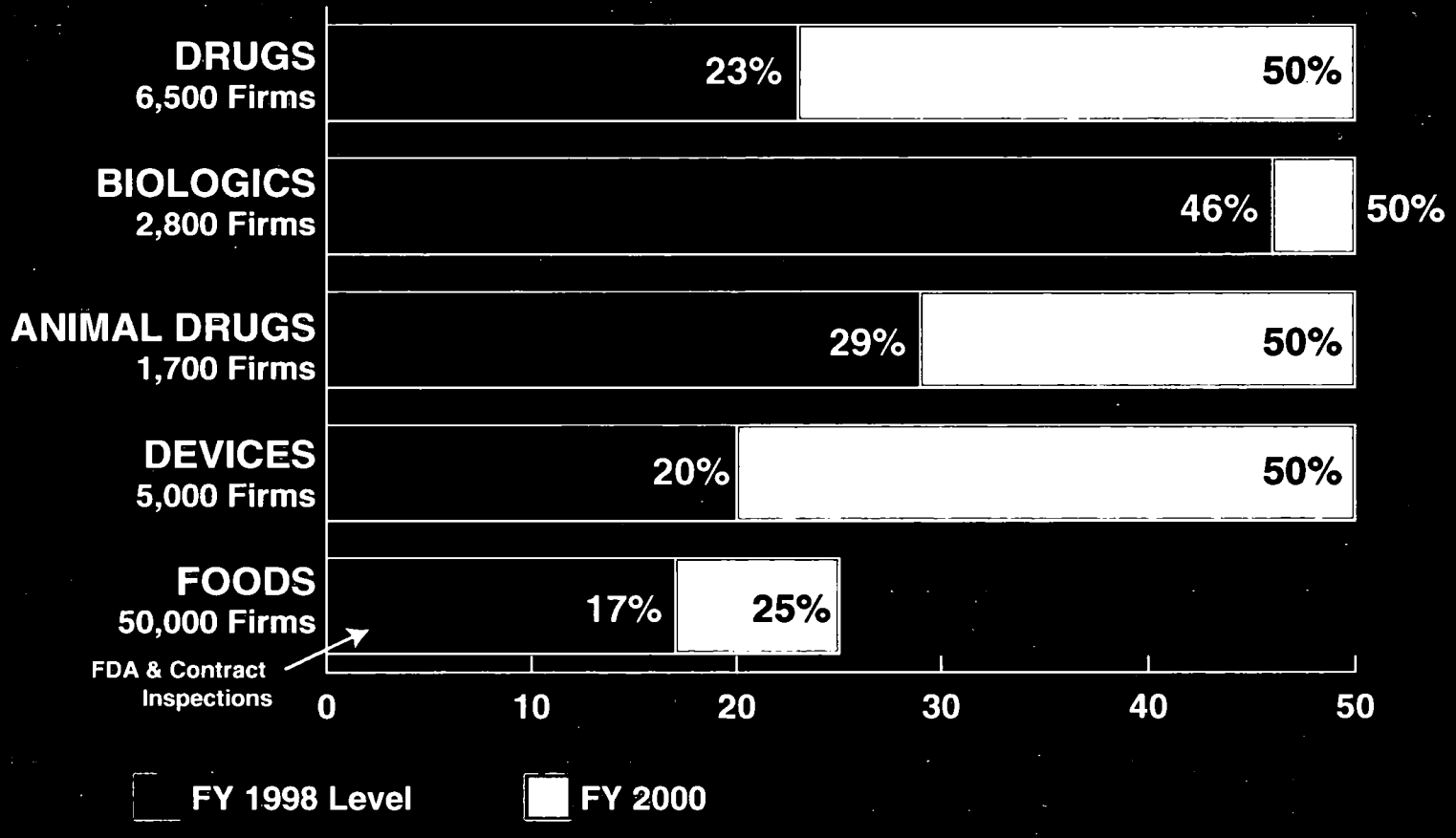
- **Adverse Event/Injury Reporting**
  (Lower the enormous cost in dollars and lives)
  - reduce injuries and healthcare costs by 15%
- **Product Safety Assurance**
  - meet 95% of statutory inspection obligation; reduce rising industry recall rates
- **Product Review**
  (Speed products to consumers; enhance industry competitiveness)
  - review 90% of product applications in statutory time frames
- **Food Safety**
  - achieve a 50% reduction in food borne illness

Injury Reporting:

What is the Problem?

- Estimated > 100,000 deaths and 1.3 million serious injuries/year in the U.S. (one of the top 6 causes of death)
- 10% of all hospital admissions from drug-related problems
- Drug-related illness and death in the U.S. cost approximately $80 billion annually
- Drug-related illness and death costs U.S. government approximately $26 billion annually

Inspection Coverage



New Product Approvals

Filling the Public Health Need