Chapter 10 – Enforcement Statistics

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Fiscal Year (FY) 2008 Enforcement Statistics Summary

FDA Enforcement Statistics Summary
Fiscal Year 2008

Seizures	8
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Convictions - OCI	369
Warning Letters	445
Recall Events	2,721
FDA 483s Issued	4,987
Inspections	15,245
Import Refusals*	17,907
Fines/Restitutions	$ 846,591,080

* **This number does not include goods returned, mail and baggage or courier shipments valued at less than $200.**

Enforcement and Inspection Statistics

Within the U.S. Food and Drug Administration (FDA or the Agency), the Office of Regulatory Affairs (ORA) is the component that is primarily responsible for conducting inspections, collection and analysis of samples, initiating enforcement actions, and the conduct of follow-up actions to assure compliance of industry and protection of the public health.

ORA's highly trained staff is on FDA's front lines of consumer protection; in airports, harbors, at our borders, in manufacturing and processing plants, in agricultural settings such as farms, feed lots, feed mills, or in fields where crops are grown, and are found in highly sophisticated laboratories. Stationed across five regions and twenty districts, ORA has more than 179 offices, resident posts, and laboratories from coast-to-coast, including Alaska, Hawaii, Puerto Rico, and the Virgin Islands. For the first time this year FDA has established a foreign footprint, opening offices in China, reflecting the Agency's efforts to ensure consumer protection in an increasingly global marketplace.

ORA Operations

ORA, is FDA's field force, its "boots on the ground." ORA is responsible for conducting foreign and domestic pre-market and post-market inspections, investigations, performing laboratory analyses, and partnering "for-cause" with states, other government agencies, and others in the conduct of its regulatory mission. Pre-market activities include bioresearch monitoring of clinical research, pre-approval inspections, laboratory method validation, and inspections of manufacturing facilities to determine if a company is able to manufacture the product to the specifications stated in its application.

ORA Operations include:
Inspecting domestic and foreign firms and clinical investigators;
Reviewing entries and physical examinations of imported products;
Collecting and analyzing product samples;
Promoting compliance through education and training;
Conducting criminal investigations of allegations of misconduct;
Working to ensure recalls protect the public health;
Collaborating with state, local, foreign, and other federal regulatory authorities to obtain information, leverage resources;
Investigating reports from consumer complaints, outbreaks of foodborne disease, and other sources;
Taking actions to respond to public health threats from natural disasters and other sources.

The largest portion of ORA's work involves post-market inspections of food, human drug, biologics, animal drug and feed, and medical device manufacturers. These post-market inspections assess manufacturers' compliance with Current Good Manufacturing Practice (CGMP) requirements. ORA's radiological health activities include inspecting certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA). ORA also

inspects radiological health products such as lasers, sunlamps, and x-ray equipment to ensure they are in compliance with performance standards.

In addition, ORA must monitor, examine, and sample imported products in each of these critical areas to ensure they meet the same rigorous safety and effectiveness standards as domestic FDA-regulated products. The Prior Notice Center receives and reviews notifications and intelligence data on food products, including animal feed, which will be imported or offered for import into the United States (U.S.), and provides guidance to the field and Customs and Border Protection (CBP) on appropriate actions related to those products. ORA's 13 laboratories perform microbiological, chemical, or radiological analyses on samples of domestic and imported FDA-regulated products.

In most areas regulated by the Agency, ORA personnel are responsible for initially evaluating whether inspectional observations and findings or other information warrants taking additional actions involving a particular establishment. ORA personnel may reinspect a firm to determine if is has made corrections to objectionable conditions observed during an inspection. ORA may also propose the issuance of formal warnings to correct violative conditions, may initiate an import alert, a seizure, an injunction, or other actions to prevent consumers from being placed at risk. ORA personnel also frequently work with firms to monitor actions taken by firms to correct objectionable conditions and are responsible for assuring that a firm's recall actions adequately protect the public health. Where there are allegations of criminal misconduct, the Office of Criminal Investigations (OCI) is responsible for investigating the allegations and working to ensure that criminal prosecutions are well-founded and supported by admissible evidence.

New Developments in FY08

The marketplace for products that FDA regulates continues to grow and is becoming increasingly international. Import entries for regulated products have steadily increased over the last five years. In FY08, ORA personnel investigated and responded to a number of large scale domestic foodborne outbreaks originating from a complex system of distribution channels spanning the globe. ORA has worked in several areas to improve its ability to monitor, investigate, and to take appropriate actions in this environment, within its available resources.

Revitalization

In January 2008, ORA issued a report, "Revitalizing ORA: Protecting the Public Health Together in a Changing World." The report examined ORA's workforce and how the tools available to perform its work could be improved. The fundamental changes

occurring in the world and their corresponding impact on ORA, the report found, dictated the development of new strategies to overcome new and old challenges. The report recommended targeted areas for improving inspection and compliance activities, enhancing the performance of its laboratories and information technology, collaborating and leveraging with other regulatory partners, and undertaking new initiatives to examine product safety and support the development of ORA's workforce and management systems. ORA is in the process of working to define and implement these targeted initiatives. This report is available at: http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4365b1_02_03_Subcommittee%20report%20on%20ORA-background.pdf

Workforce Challenges

Although ORA accounts for about one-third of all FDA employees, it has experienced a decline in staffing over the past several years, losing approximately 800 personnel since 2003. Fiscal year (FY) 07 brought change to ORA's budget that allowed ORA to do its first wide-scale hiring in four years, hiring 104 new investigators in targeted locations. FY08-09 offered additional hiring opportunities which are currently underway. These new hires will require intensive training, coaching and supervision at the hands of more experienced ORA personnel to achieve independence and it will take even longer before they will be ready to independently assume all of their diverse and complex responsibilities. Training of both new and current employees will be critical to fill the gaps created by the loss of expertise over the last few years and by the increasing complexity of FDA-regulated products and their manufacturing process.

Foreign Inspections

To supplement knowledge gained from foreign regulatory counterparts, ORA conducts inspections of foreign facilities that offer FDA-regulated products for import into the U.S. These products include every type subject to FDA regulation and come from more than 230 countries and more than 300,000 manufacturers. In FY07, ORA inspected 1,003 foreign facilities, the largest number of foreign inspections in a fiscal year by ORA to date. In FY08, ORA inspected 947 foreign facilities. FDA has committed to increasing the numbers of targeted foreign inspections and the development of improved relationships, and sharing information with foreign regulatory partners will help the Agency to identify problem products before they are offered for import and enter U.S. commerce.

Statistics Overview

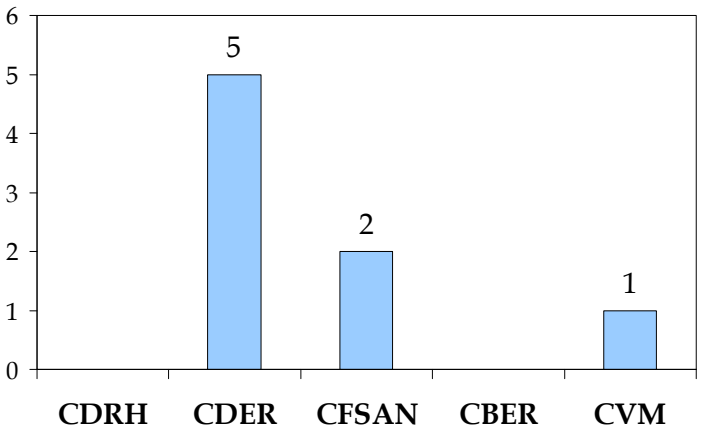
In FY08 FDA conducted 14,298 domestic inspections and performed 947 inspections of foreign facilities and 24,260 import sample collections, reflecting the focus on the global environment, precipitated by findings of public health issues in infant formula, heparin and others. Criminal investigations conducted in FY08 resulted in more than $860 million in fines and restitution, as well as a record number of convictions. In civil cases, we have seen an increase in seizures from last year, while the number of injunctions has declined.

The following pages provide summary data for FY08 activities. The actions described in previous chapters and the data provided here describe many of the product areas over which FDA has jurisdiction. The Enforcement Story is not intended to describe the universe of all of the Agency's actions but instead is a summary representation of some of our most important actions to protect the public health.

This year's story includes accounts of expanding international collaborations, and increased focus on global threats to domestic consumers but not to the exclusion of providing stories of critical domestic operations. FDA proactively monitors domestic firms and the foods, drugs, and medical devices that they produce, imported products, and foreign firms exporting products to U.S. markets. Whether through research and methods development, inspection, investigation, sampling, recall, seizure, injunction, or criminal prosecution, FDA has acted over the last year and continues to act to protect U.S. consumers from unsafe products. These domestic activities, combined with FDA's foreign initiatives form an integrated and cohesive enforcement strategy in protecting the public health and ensuring our consumers are safe.

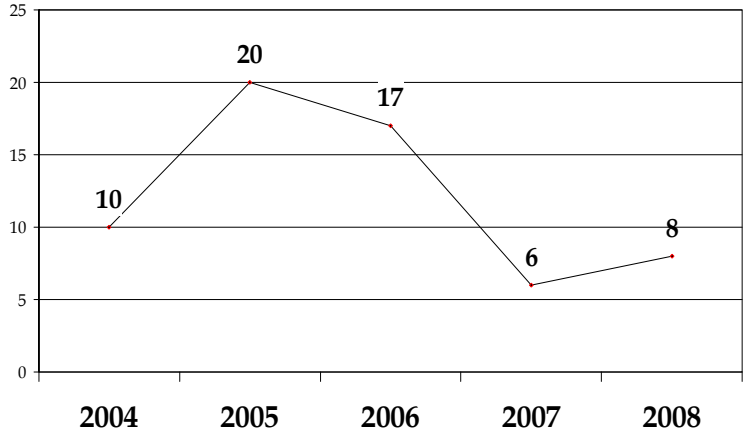
Seizures and Injunctions

Seizures by FDA Center*
Fiscal Year 2008



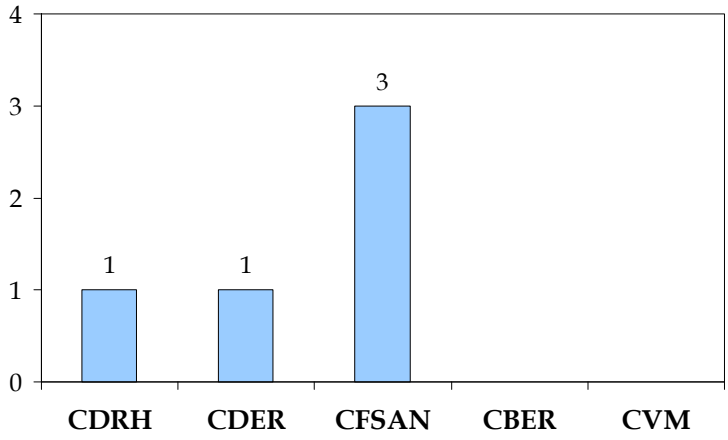
* NB: A single seizure may involve more than one Center's products.

FDA Seizures*
Fiscal Years 2004 – 2008

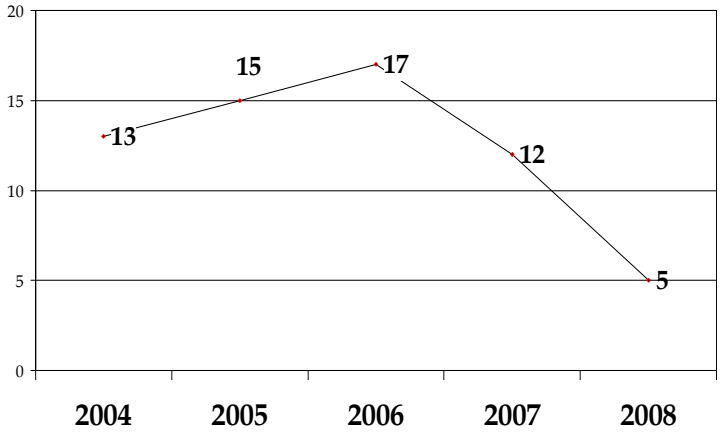


* NB: A single seizure may involve more than one Center's products.

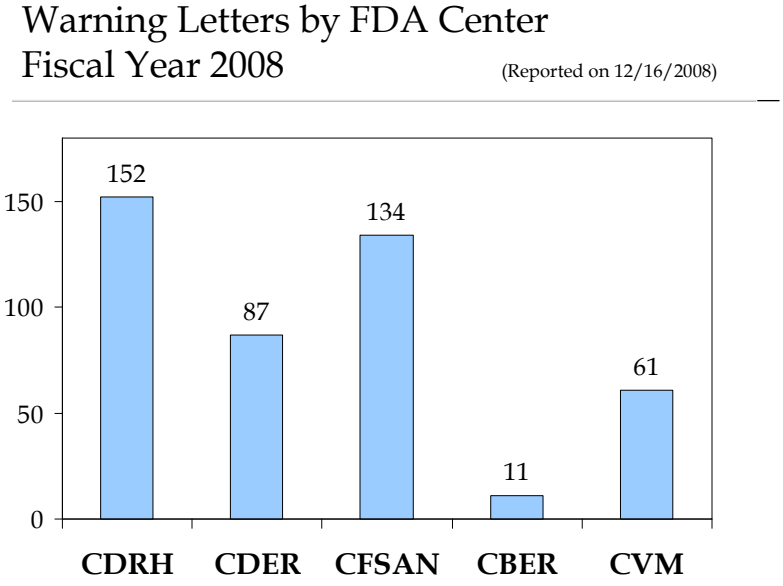
Injunctions by FDA Center
Fiscal Year 2008

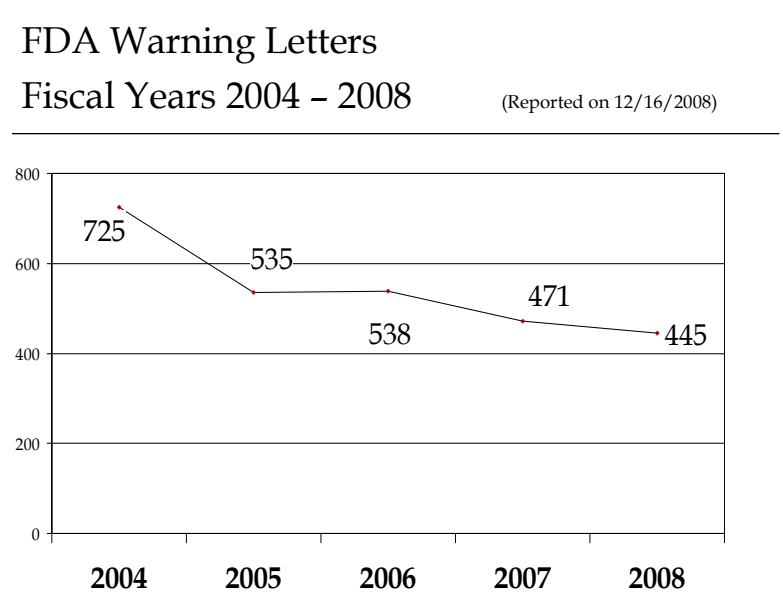


FDA Injunctions
Fiscal Years 2004 - 2008



Warning Letters

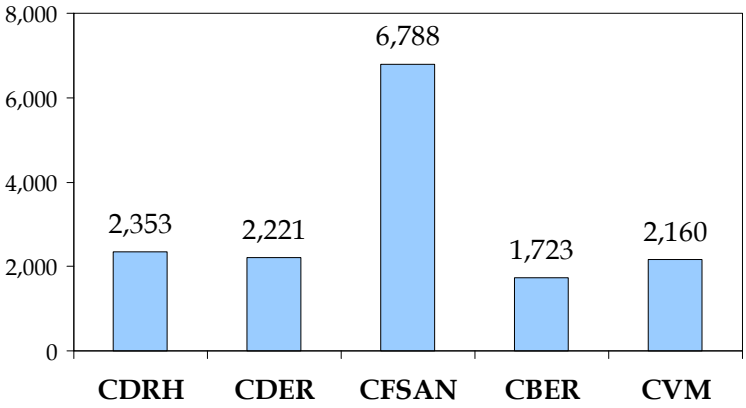




Inspections

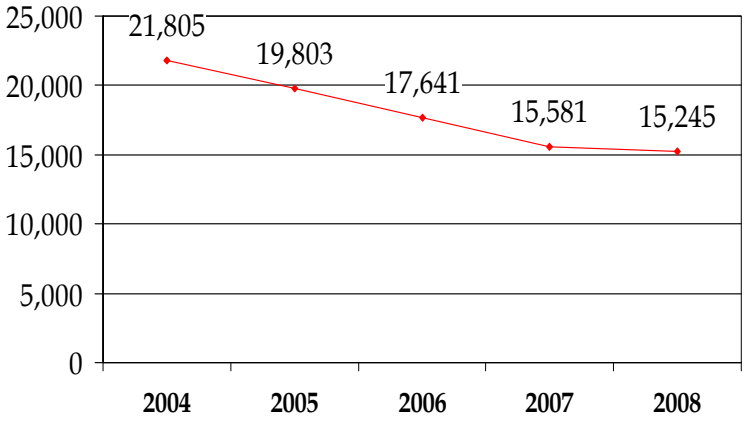
Inspections by FDA Center
Fiscal Year 2008

(Reported on 1/06/2009)



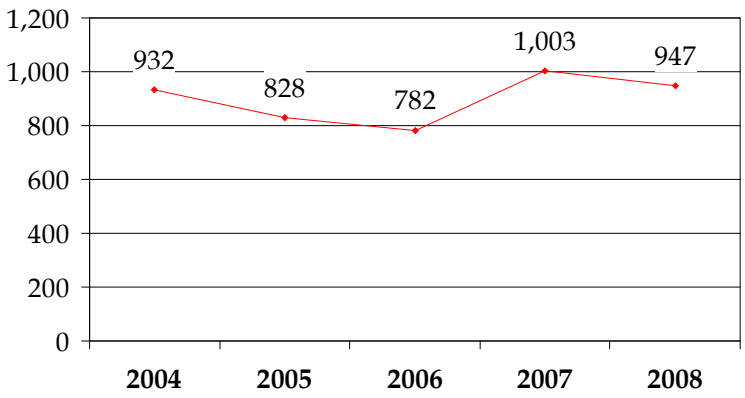
Total Foreign and Domestic Inspections
Fiscal Years 2004 – 2008

(Reported on 1/06/2009)



Total Foreign Inspections
Fiscal Years 2004 – 2008

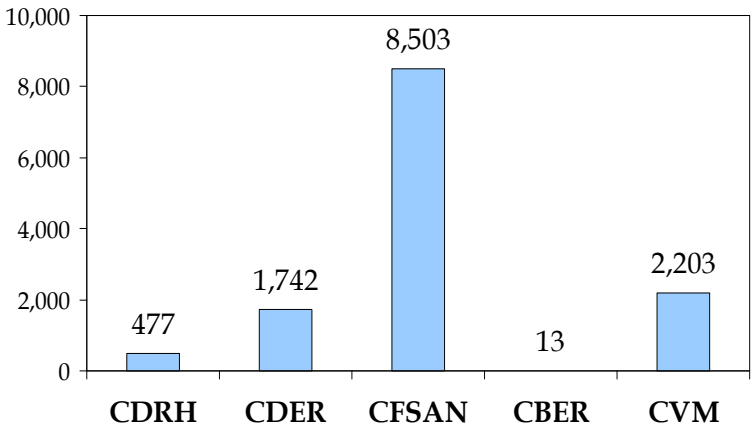
(Reported on 1/06/2009)



Sample Collection

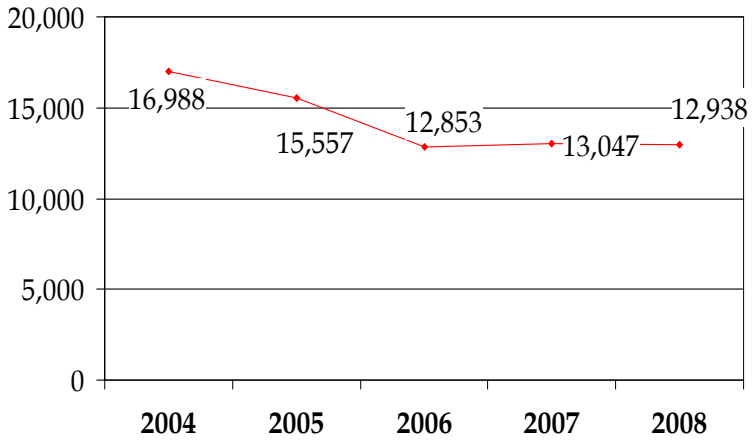
Domestic Samples Collected - By Center
Fiscal Year 2008

(Reported on 1/06/2009)



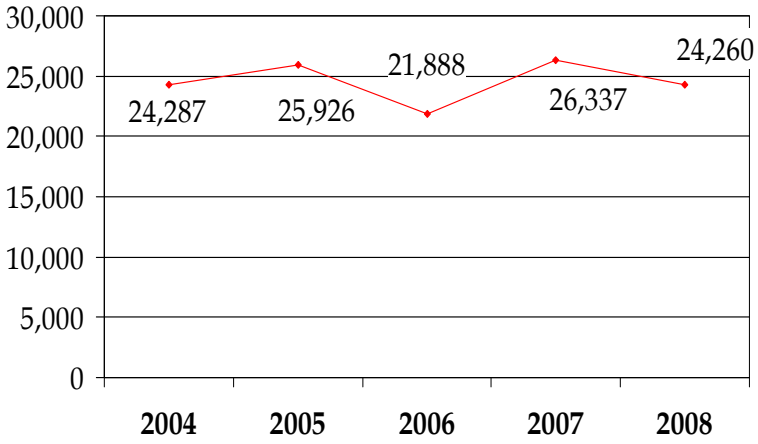
Domestic Samples Collected
Fiscal Years 2004 – 2008

(Reported on 1/06/2009)



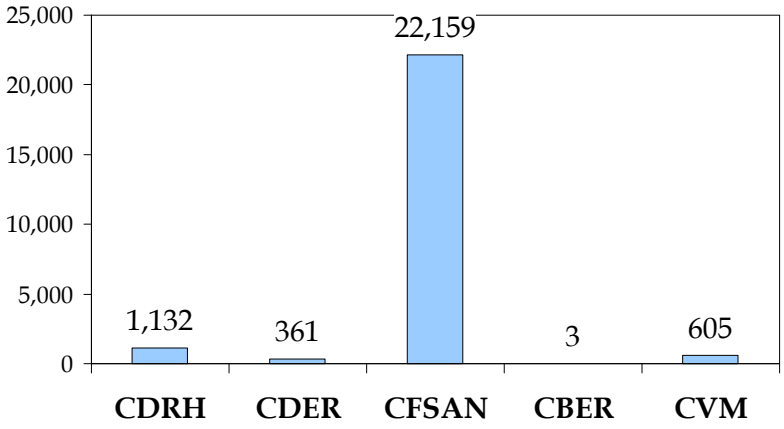
Import Samples
Fiscal Years 2004 – 2008

(Reported on 1/06/2009)

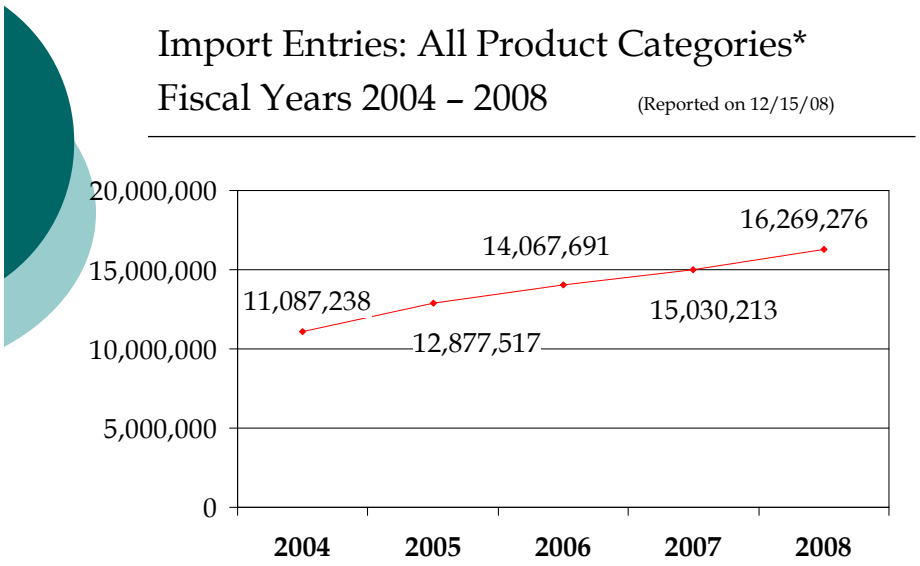


Import Samples Collected - By Center
Fiscal Year 2008

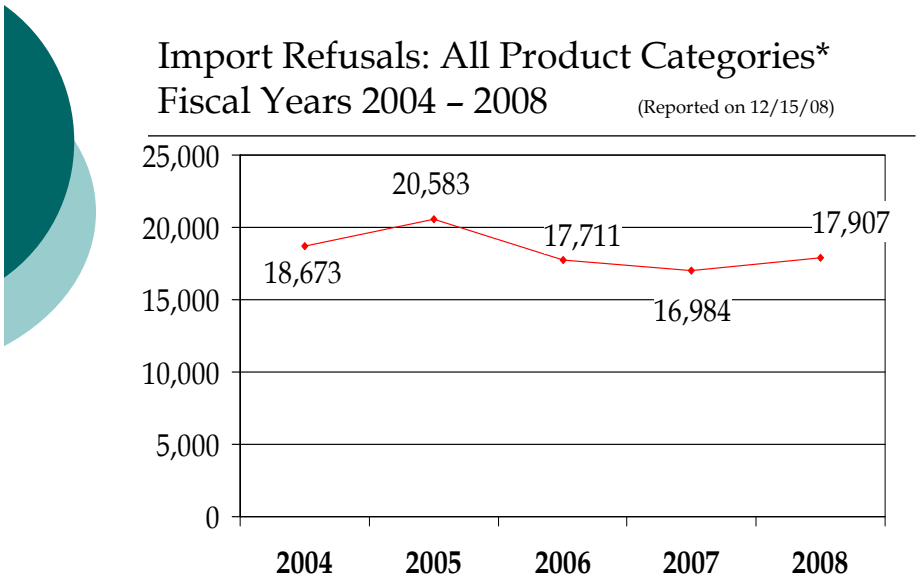
(Reported on 1/06/2009)



Import Entries & Refusals



***These data have been extracted to accurately report import refusals for FY 2004 to the present. These numbers do not include goods returned, mail and baggage or courier shipments valued at less than $200. These data are not comparable to data reported in the FY07 Enforcement Story for Import Refusals.**



***These data have been extracted to accurately report import refusals for FY 2004 to the present. These numbers do not include goods returned, mail and baggage or courier shipments valued at less than $200. These data are not comparable to data reported in the FY07 Enforcement Story for Import Refusals.**

Recalls

Recalls: Definition of Class I, II and III

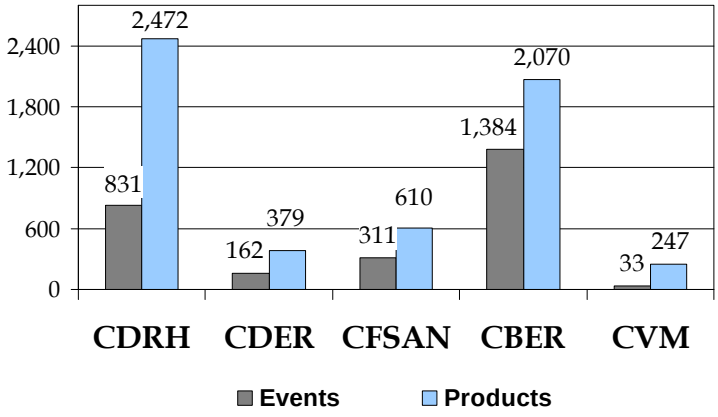
Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

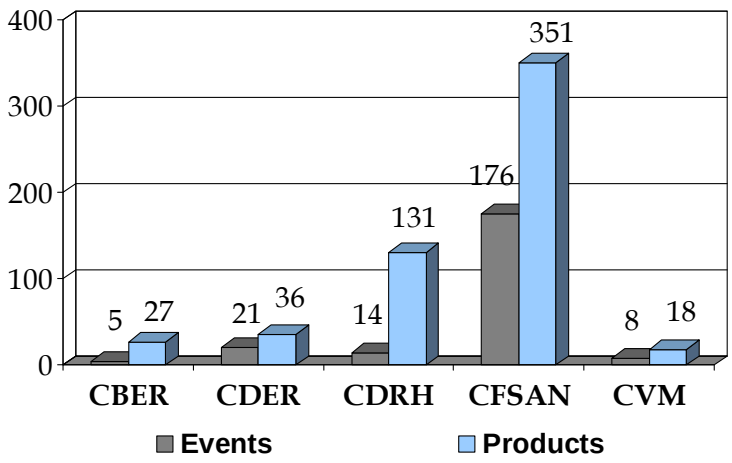
FDA Recalls Fiscal Year 2008 By Center - All Classes

(Reported on 11/20/2008)



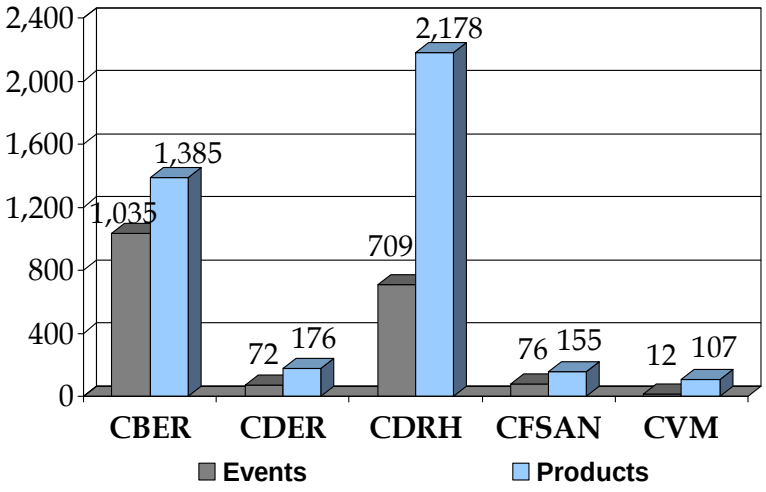
FDA Recalls - Fiscal Year 2008
Class I By Center

(Reported on 11/20/2008)



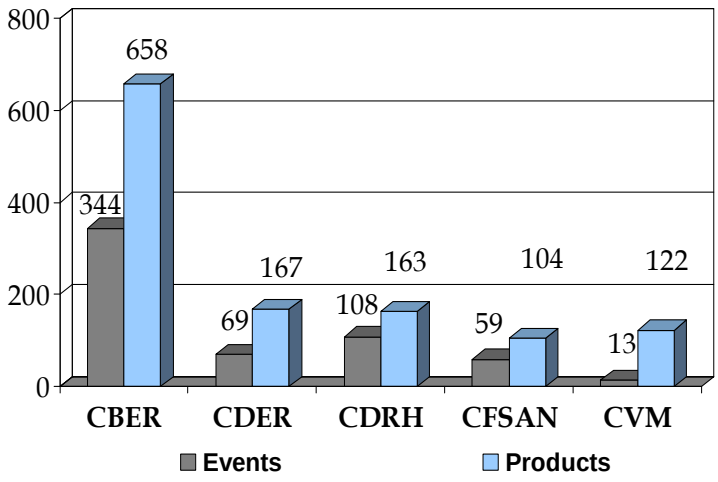
FDA Recalls - Fiscal Year 2008
Class II By Center

(Reported on 11/20/2008)



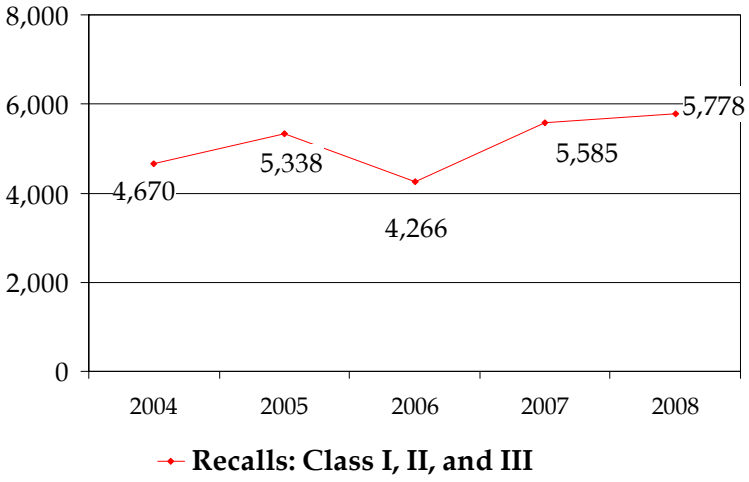
FDA Recalls - Fiscal Year 2008
Class III By Center

(Reported on 11/20/2008)



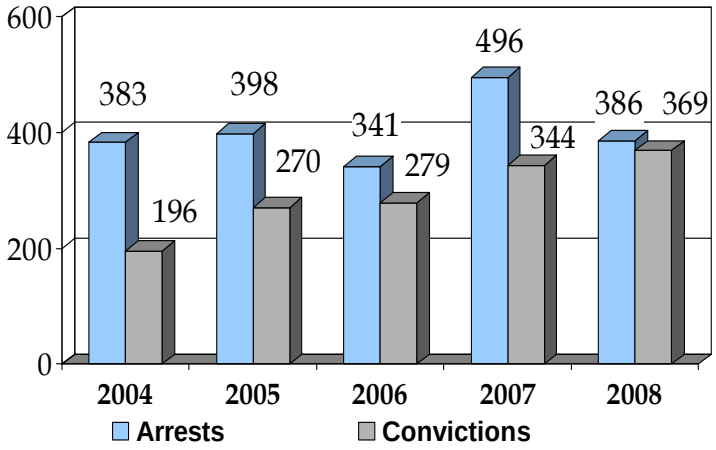
Recalled Products – All Centers
Fiscal Years 2004 – 2008

(Reported on 11/20/2008)



Arrests & Convictions

FDA Office of Criminal Investigations
Fiscal Years 2004 – 2008 (Reported on 11/18/2008)



Glossary

COMPLIANCE ACHIEVEMENT: The observed repair, modification, or adjustment of a violative condition, or the repair, modification, adjustment, relabeling, or destruction of a violative product when either the product or condition does not comply with the Acts enforced by the Agency.

CIVIL MONEY PENALTY: A monetary penalty for a non-criminal action that is assessed by FDA or the courts for violations of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

INDICTMENT: A formal accusation by a grand jury that sets forth charges against a defendant and states when the alleged crime occurred. An indictment is not a finding of guilt.

INJUNCTION: A civil action taken against an individual or firm seeking to stop continued production or distribution of a violative product.

NOTICE OF INSPECTIONAL OBSERVATIONS (FDA-483): The document lists observations made by the FDA representative(s) during an inspection of a facility.

PROSECUTION: A criminal action taken against a company or individual charging violation of the law.

RECALL AND FIELD CORRECTION: An action taken by a firm to either remove a violative product from the market or to conduct a field correction. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the product is located. A U.S. Marshal is then directed by the court to take possession of the goods until the matter is resolved.

WARNING LETTER: An informal advisory to a firm communicating the Agency's

position on a matter but does not commit FDA to taking enforcement action. The Agency's policy is that Warning Letters should be issued for violations which are of regulatory significance in that failure to adequately and promptly take corrections may be expected to result in enforcement action should the violation(s) continue.

For the purpose of the charts and graphs the following descriptive terms are used:

ADVERSE FINDINGS: The number of establishment inspections classified "Official Action Indicated" or "Voluntary Action Indicated" and the number of samples analyzed and classified as violative.

INDUSTRY SURVEILLANCE: The total number of establishment inspections, sample collections, field examinations and wharf examinations conducted by FDA personnel.

Acronyms

AABB	American Association of Blood Banks
"the Act"	Food, Drug, and Cosmetic Act
ACD	Anticoagulant Citrate Dextrose
AED	automatic external defibrillator
AIDS	acquired immune deficiency syndrome
ALS	amyotrophic lateral sclerosis
ANDA	abbreviated new drug application
APA	Administrative Procedures Act
API	active pharmaceutical ingredient
AQSIQ	Chinese General Administration of Quality Supervision, Inspection and Quarantine
ARC	American Red Cross
ATF	Bureau of Alcohol, Tobacco, and Firearms
BHRT	bio-identical hormone replacement therapy
BIMO	bioresearch monitoring
BSE	bovine spongiform encephalopathy (mad cow disease)
C. botulinum	*Clostridium botulinum*
CAPA	corrective and preventive action
CBER	Center for Biologics Evaluation and Research
CBP	Customs and Border Protection
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CEO	Chief Executive Officer
CF	cystic fibrosis
CFO	Chief Financial Officer
CFP	ciguatera fish poisoning
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CGMP	Current Good Manufacturing Practice
CMO	Chief Medical Officer
CFN	central file number
COMSTAT	Compliance Status Information System
CPB	Compliance Programs Branch

CPG	Compliance Policy Guide
CRT-D	cardiac resynchronization therapy-defibrillator
CSO	consumer safety officer
CVM	Center for Veterinary Medicine
dba	doing business as
DCIS	Defense Criminal Investigative Service
DDMAC	Division of Drug Marketing, Advertising and Communication
DEA	Drug Enforcement Administration
DFSR	Division of Federal-State Relations
DNP	dinitrophenol
DOD	Department of Defense
DSI	Division of Scientific Investigations
ECG	electrocardiogram
ED	erectile dysfunction
EIR	establishment inspection report
eLEXNET	Electronic Laboratory Exchange Network
EU	European Union
FBI	Federal Bureau of Investigation
FCC	Forensic Chemistry Center
FDA	Food and Drug Administration
FDAAA	Food and Drugs Administration Amendments Act
FDCA	Food, Drug, and Cosmetic Act
FDSA	Food Defense Surveillance Assignment
FEI	FDA establishment identifier
FERN	Food Emergency Response Network
FPP	Food Protection Plan
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
FWS	U.S. Fish & Wildlife Service
FY	fiscal year
GAO	Government Accountability Office
GCP	good clinical practices
GWQAP	Government Wide Quality Assurance Program
HACCP	Hazard Analysis and Critical Control Point
HCT/P	human cellular and tissue-based products
HGH	human growth hormone

HHS	Health and Human Services
HIV	human immunodeficiency virus
IA	Import Alert
ICD	implantable cardioverter defibrillator
ICE	Immigration and Customs Enforcement
ICH	International Conference on Harmonisation
IDE	investigational device exemption
IMF	international mail facility
IND	investigational new drug
INDA	investigational new drug application
IOR	Importer of Record
IRB	Institutional Review Board or Investigational Review Board
ISAP	Import Safety Action Plan or Action Plan for Import Safety
IT	information technology
LACF	low acid canned food
MARCS	Mission Accomplishment and Regulatory Compliance Services
MDR	medical device reporting
MOA	Memoranda of Agreement
MOU	Memorandum of Understanding
MQSA	Mammography Quality Standards Act of 1992
MRT	Mail Review Team
NCIMS	National Conference on Interstate Milk Shipments
NDA	New Drug Application
NPO	National Program Office
OBRR	Office of Blood Research and Review
OC	Office of Compliance
OCAC	Office of Cosmetics and Colors
OCI	Office of Criminal Investigations
OEM	original equipment manufacturer
OIVD	Office of In-Vitro Diagnostic Device Evaluation and Safety
OMB	Office of Management and Budget
OOS	out of specification
ORA	Office of Regulatory Affairs

Order	Order of Need for Emergency Permit
OTC	over-the-counter
PHSA	Public Health Services Act
PI	package insert or product labeling
"the Plan"	Food Protection Plan
PMA	premarket approval
PMS	premenstrual syndrome
ppm	parts per million
PSA	Protein Surveillance Assignment
PSP	Paralytic Shellfish Poisoning
QA	quality assurance
QCU	Quality Control Unit
QS	Quality System
SEFDA	Special Event Food Defense Assignment
SFDA	Chinese State Food and Drug Administration
SOP	standard operating procedure
STD	sexually transmitted diseases
U.S.	United States
U.S.C.	United States Code
USDA	U.S. Department of Agriculture
USP	U.S. Pharmacopeia
VA	Veterans Administration
vCJD	variant Creutzfeldt Jakob Disease
WHO	World Health Organization
510(k)	section of the Food, Drug, and Cosmetic Act that deals with premarket notification