
Fiscal Year (FY) 2008 Enforcement Statistics Summary



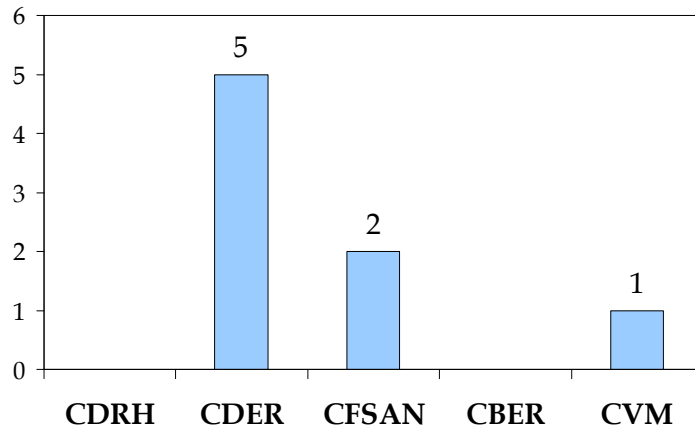
FDA Enforcement Statistics Summary Fiscal Year 2008

Seizures	8
Injunctions	5
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.

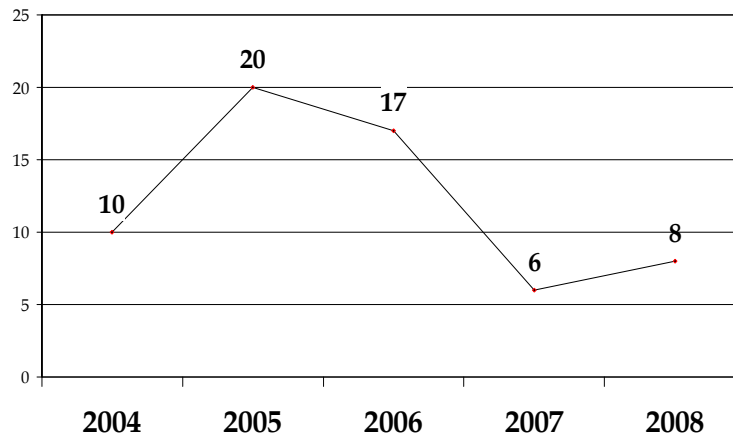
Seizures and Injunctions

Seizures by FDA Center*
Fiscal Year 2008



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

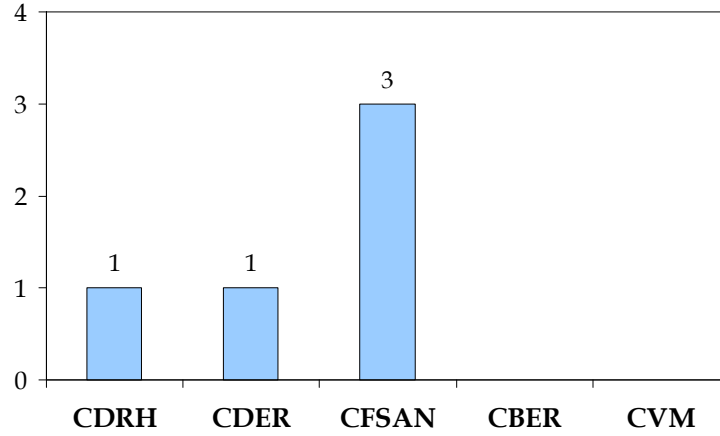
FDA Seizures*
Fiscal Years 2004 - 2008



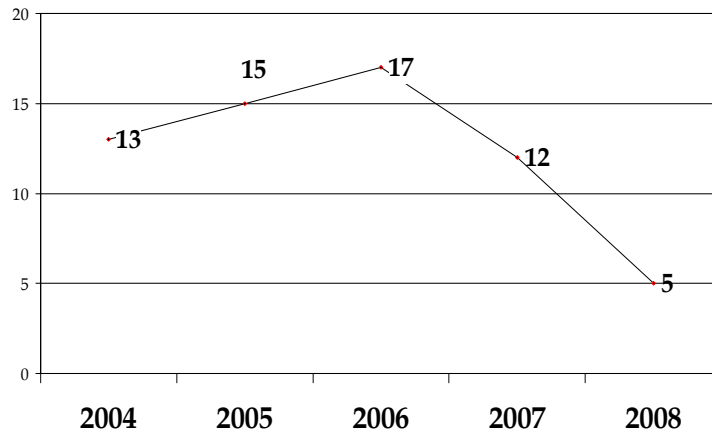
* NB: A single seizure may involve more than one Center's products.



Injunctions by FDA Center Fiscal Year 2008



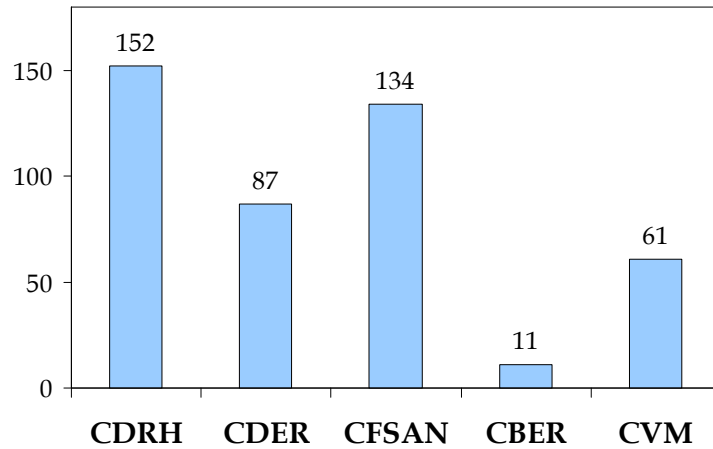
FDA Injunctions Fiscal Years 2004 - 2008



Warning Letters

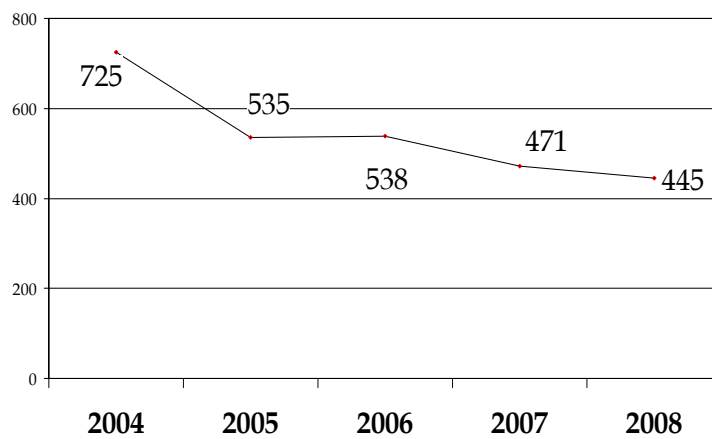
Warning Letters by FDA Center
Fiscal Year 2008

(Reported on 12/16/2008)



FDA Warning Letters
Fiscal Years 2004 - 2008

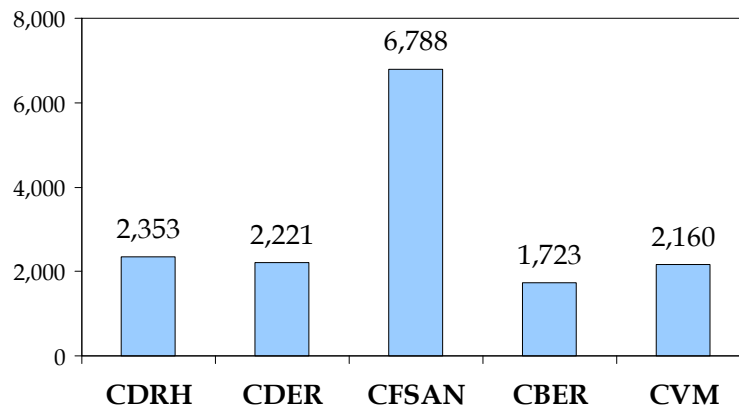
(Reported on 12/16/2008)



Inspections

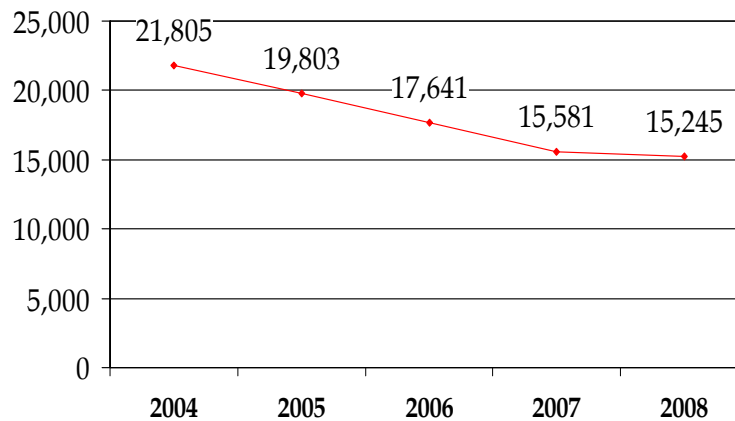
Inspections by FDA Center
Fiscal Year 2008

(Reported on 1/06/2009)



Total Foreign and Domestic Inspections
Fiscal Years 2004 - 2008

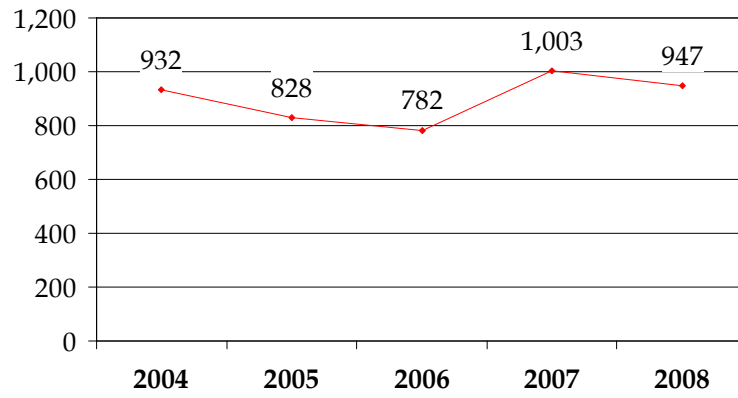
(Reported on 1/06/2009)





Total Foreign Inspections Fiscal Years 2004 - 2008

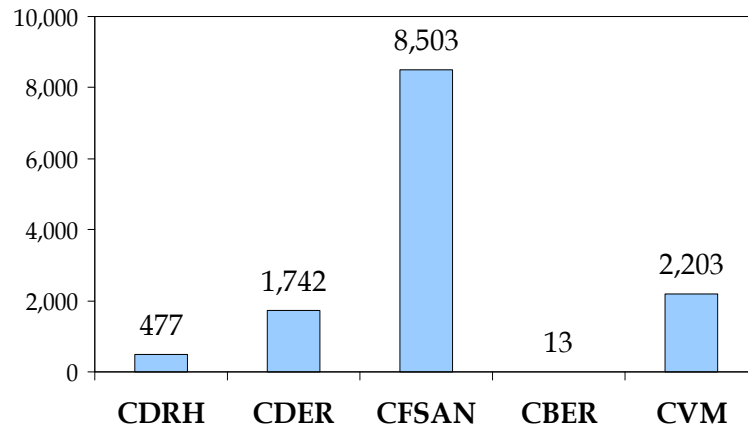
(Reported on 1/06/2009)



Sample Collection

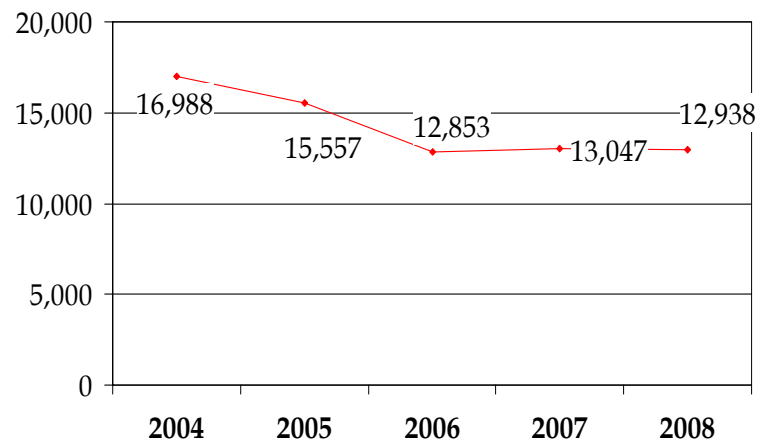
Domestic Samples Collected - By Center
Fiscal Year 2008

(Reported on 1/06/2009)



Domestic Samples Collected
Fiscal Years 2004 - 2008

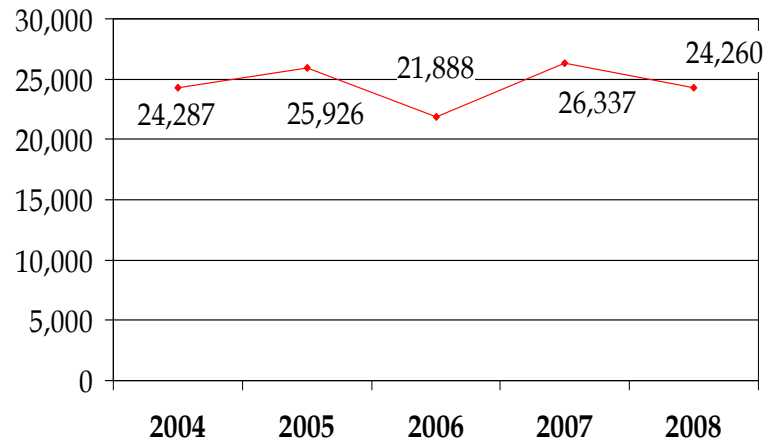
(Reported on 1/06/2009)





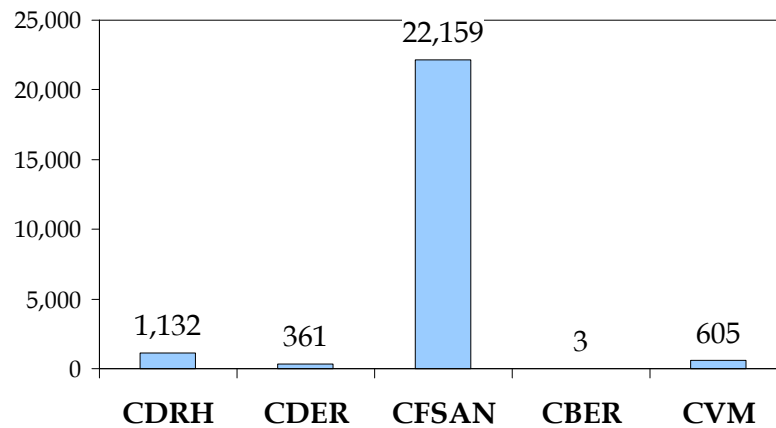
Import Samples Fiscal Years 2004 - 2008

(Reported on 1/06/2009)



Import Samples Collected - By Center Fiscal Year 2008

(Reported on 1/06/2009)

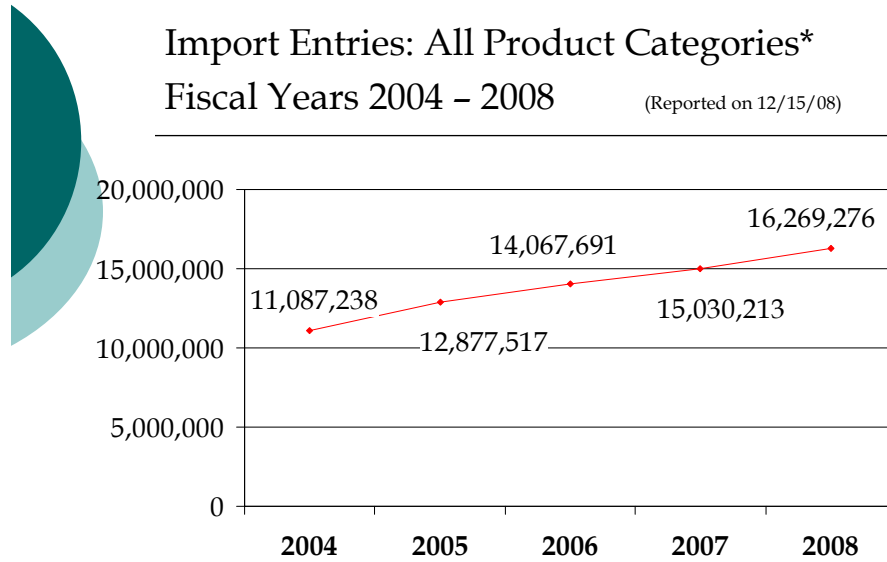


Import Entries & Refusals

Import Entries: All Product Categories*

Fiscal Years 2004 – 2008

(Reported on 12/15/08)

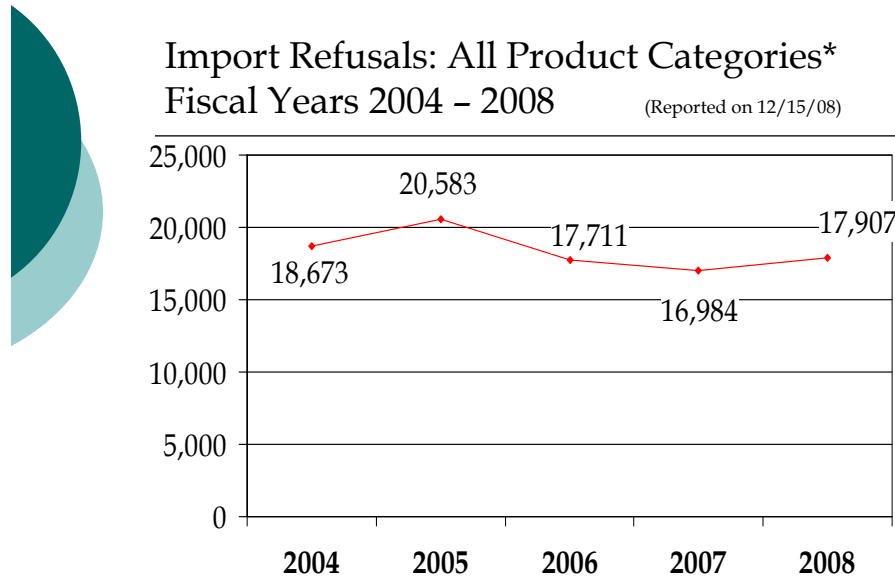


*These data have been extracted to accurately report import refusals for FY 2004 to the present. These numbers do not include goods returned, mail and baggage or courier shipments valued at less than \$200. These data are not comparable to data reported in the FY07 Enforcement Story for Import Refusals.

Import Refusals: All Product Categories*

Fiscal Years 2004 – 2008

(Reported on 12/15/08)



*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

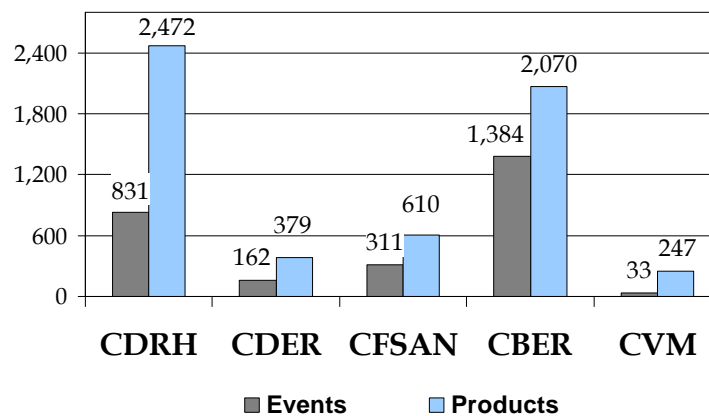
Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

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

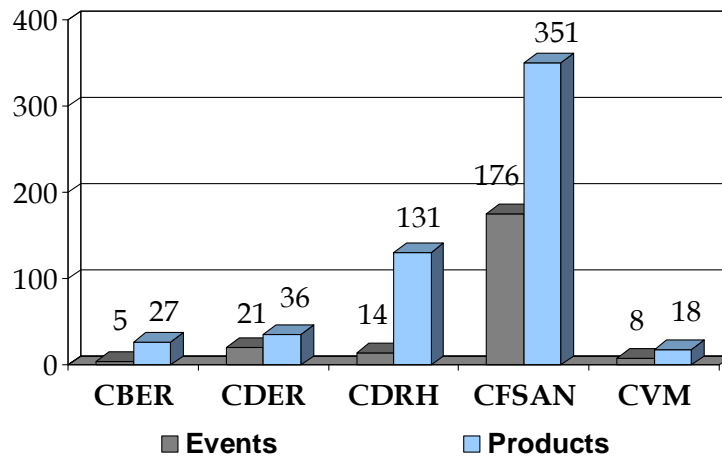
(Reported on 11/20/2008)





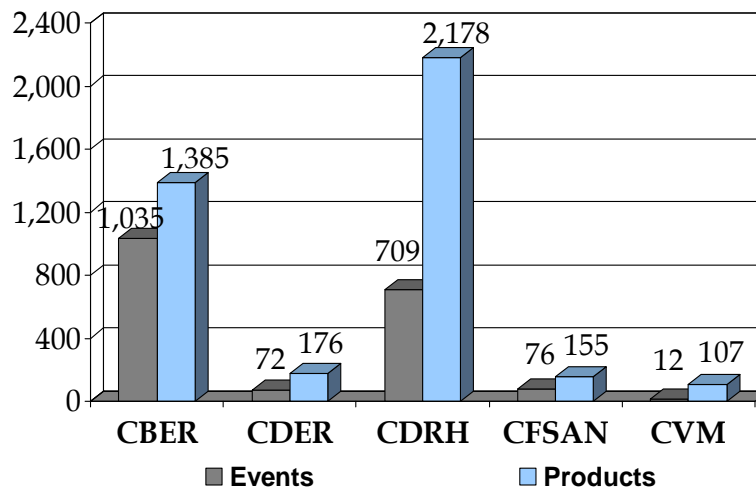
FDA Recalls - Fiscal Year 2008 Class I By Center

(Reported on 11/20/2008)



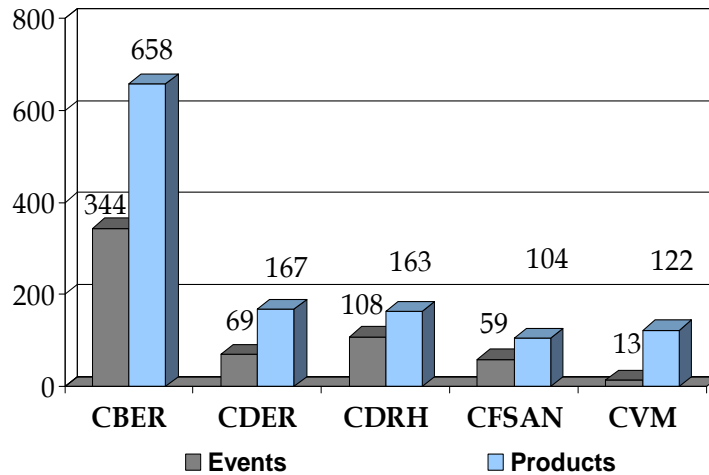
FDA Recalls - Fiscal Year 2008 Class II By Center

(Reported on 11/20/2008)



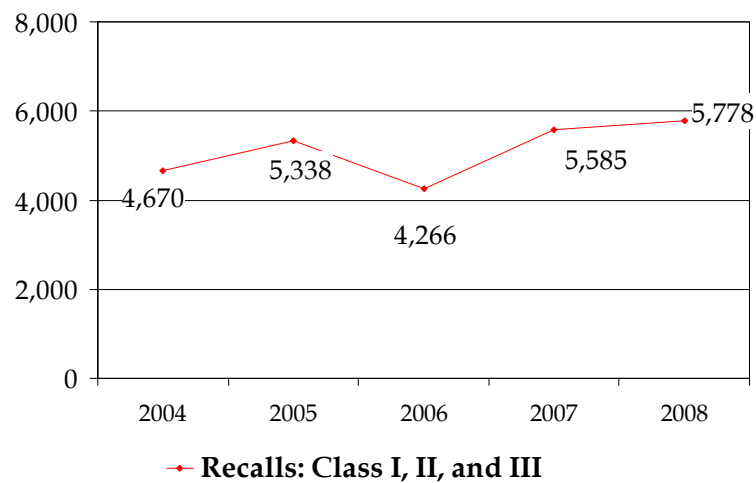
FDA Recalls - Fiscal Year 2008 Class III By Center

(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)

