Fiscal Year (FY) 2008 Enforcement Statistics Summary

FDA Enforcement Statistics Summary
Fiscal Year 2008

<table>
<thead>
<tr>
<th>Seizures</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injunctions</td>
<td>5</td>
</tr>
<tr>
<td>Convictions - OCI</td>
<td>369</td>
</tr>
<tr>
<td>Warning Letters</td>
<td>445</td>
</tr>
<tr>
<td>Recall Events</td>
<td>2,721</td>
</tr>
<tr>
<td>FDA 483s Issued</td>
<td>4,987</td>
</tr>
<tr>
<td>Inspections</td>
<td>15,245</td>
</tr>
<tr>
<td>Import Refusals*</td>
<td>17,907</td>
</tr>
<tr>
<td>Fines/Restitutions</td>
<td>$846,591,080</td>
</tr>
</tbody>
</table>

* 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

CDRH   CDER   CFSAN   CBER   CVM

0   1   1   3   0   2   2   2   2   2

FDA Injunctions
Fiscal Years 2004 - 2008

2004  2005  2006  2007  2008

13  15  17  12  5
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)

<table>
<thead>
<tr>
<th>Center</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDRH</td>
<td>2,353</td>
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<tr>
<td>CDER</td>
<td>2,221</td>
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<tr>
<td>CFSAN</td>
<td>6,788</td>
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<tr>
<td>CBER</td>
<td>1,723</td>
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<tr>
<td>CVM</td>
<td>2,160</td>
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</tr>
</tbody>
</table>

Total Foreign and Domestic Inspections
Fiscal Years 2004 – 2008

(Reported on 1/06/2009)

Year | Inspections
--- | ---
2004 | 21,805
2005 | 19,803
2006 | 17,641
2007 | 15,581
2008 | 15,245
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.

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FDA Recalls Fiscal Year 2008
By Center - All Classes (Reported on 11/20/2008)

![Bar chart](https://example.com/bar-chart.png)
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)