## FDA Enforcement Statistics Summary

Fiscal Year 2009

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seizures</td>
<td>8</td>
</tr>
<tr>
<td>Injunctions</td>
<td>11</td>
</tr>
<tr>
<td>Warning Letters</td>
<td>474</td>
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<tr>
<td>Recall Events</td>
<td>2,781</td>
</tr>
<tr>
<td>Recalled Products</td>
<td>8,065</td>
</tr>
<tr>
<td>Debarments</td>
<td>6</td>
</tr>
</tbody>
</table>
Seizures by FDA Center
Fiscal Year 2009

- CDRH: 0
- CDER: 3
- CFSAN: 4
- CBER: 0
- CVM: 1
FDA Seizures
Fiscal Years 2004 – 2009
Injunctions by FDA Center Fiscal Year 2009

- CDRH: 0
- CDER: 2
- CFSAN: 5
- CBER: 0
- CVM: 4
FDA Injunctions
Fiscal Years 2004 - 2009
Warning Letters by FDA Center
Fiscal Year 2009

CDRH: 136
CDER: 112
CFSAN: 153
CBER: 19
CVM: 54
FDA Warning Letters
Fiscal Years 2004 – 2009

2004 2005 2006 2007 2008 2009

725 535 538 471 445 474
Total Recall Events by FDA Center
Fiscal Year 2009

Class I, II and III

- CDRH: 776
- CDER: 207
- CFSAN: 517
- CBER: 1,237
- CVM: 44
Total Recalled Products by FDA Center
Fiscal Year 2009

![Bar chart showing the total recalled products by FDA Center for Class I, II, and III.](chart_image)
FDA Recalls By Center - All Classes
Fiscal Year 2009

- CDRH: 2,306 (Events: 776, Products: 1,530)
- CDER: 1,984 (Events: 207, Products: 1,777)
- CFSAN: 1,728 (Events: 517, Products: 1,211)
- CBER: 1,763 (Events: 1,237, Products: 526)
- CVM: 44 (Events: 44, Products: 0)
FDA Recalls - Fiscal Year 2009
Class I By Center

CFSAN: 1,457
CDER: 30
CDRH: 32
CVM: 7
CBER: 0

Events
Products
Recalled Products – All Centers
Fiscal Years 2004 – 2009

Recalls: Class I, II, and III
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.