# FDA Enforcement Statistics Summary

### Fiscal Year 2010

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
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<tbody>
<tr>
<td>Seizures</td>
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<tr>
<td>Injunctions</td>
<td>17</td>
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<tr>
<td>Warning Letters</td>
<td>673</td>
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<tr>
<td>Recall Events</td>
<td>3,799</td>
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<tr>
<td>Recalled Products</td>
<td>9,361</td>
</tr>
<tr>
<td>Debarments</td>
<td>13</td>
</tr>
</tbody>
</table>
FDA Seizures
Fiscal Years 2004 – 2010

2004 2005 2006 2007 2008 2009 2010
Injunctions by FDA Center
Fiscal Year 2010

CDRH  CDER  CFSAN  CBER  CVM  CTP
2      1      10     1      3    0
FDA Injunctions
Fiscal Years 2004 - 2010
Warning Letters by FDA Center Fiscal Year 2010

- CDRH: 204
- CDER: 171
- CFSAN: 191
- CBER: 15
- CVM: 71
- CTP: 21
Total Recall Events by FDA Center
Fiscal Year 2010

Class I, II and III

CDRH 876
CDER 258
CFSAN 738
CBER 1,881
CVM 46
CTP 0
Total Recalled Products by FDA Center
Fiscal Year 2010

Class I, II and III

CDRH | CDER | CFSAN | CBER | CVM | CTP
--- | --- | --- | --- | --- | ---
2,634 | 868 | 2,938 | 2,724 | 197 | 0
FDA Recalls By Center - All Classes
Fiscal Year 2010

<table>
<thead>
<tr>
<th>Center</th>
<th>Events</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDRH</td>
<td>876</td>
<td>2,634</td>
</tr>
<tr>
<td>CDER</td>
<td>258</td>
<td>868</td>
</tr>
<tr>
<td>CFSAN</td>
<td>738</td>
<td>2,938</td>
</tr>
<tr>
<td>CBER</td>
<td>1,881</td>
<td>2,724</td>
</tr>
<tr>
<td>CVM</td>
<td>46</td>
<td>197</td>
</tr>
</tbody>
</table>
FDA Recalls - Fiscal Year 2010
Class I By Center

![Bar Chart]

- **CDRH**: 49 Events, 334 Products
- **CDER**: 29 Events, 158 Products
- **CFSAN**: 498 Events, 2,235 Products
- **CBER**: 1 Event, 2 Products
- **CVM**: 11 Events, 41 Products

Legend:
- Gray: Events
- Blue: Products
FDA Recalls - Fiscal Year 2010
Class II By Center

![Bar Chart](chart.png)
FDA Recalls - Fiscal Year 2010
Class III By Center

- CDRH: 74 Events, 92 Products
- CDER: 91 Events, 321 Products
- CFSAN: 46 Events, 139 Products
- CBER: 11 Events, 634 Products
- CVM: 31 Products
Recalled Products – All Centers
Fiscal Years 2004 – 2010

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.