Enforcement Statistics

Center for Biologics Evaluation and Research
FDA Foreign and Domestic Inspections
Fiscal Years 2004 - 2008

Center for Biologics Evaluation and Research
Surveillance: Import and Domestic Samples
Fiscal Years 2004 - 2008
**Center for Biologics Evaluation and Research**

**Enforcement Activity**

**Fiscal Years 2004 - 2008**

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Enforcement Activity</th>
</tr>
</thead>
</table>
| 2008        | - Penalty assessed of $1,668,000 for violations in blood banks under permanent injunction  
              - Penalty assessed of $4,614,000 for violations in blood banks under permanent injunction  
              - One Clinical Investigator Disqualification |
| 2007        | - One Clinical Investigator Disqualification |
| 2006        | - None |
| 2005        | - One Clinical Investigator Disqualification |
| 2004        | - One Clinical Investigator Disqualification |

---

**Center for Biologics Evaluation and Research**

**Five-Year Total Product Recall Statistics**

**Fiscal Years 2004 - 2008**

![Graph showing five-year total product recall statistics](chart.png)

- **Class I**
  - 2004: 6  
  - 2005: 538  
  - 2006: 601  
  - 2007: 13  
  - 2008: 116  

- **Class II**
  - 2004: 1  
  - 2005: 1  
  - 2006: 451  
  - 2007: 116  
  - 2008: 384  

- **Class III**
  - 2004: 0  
  - 2005: 0  
  - 2006: 27  
  - 2007: 27  
  - 2008: 658