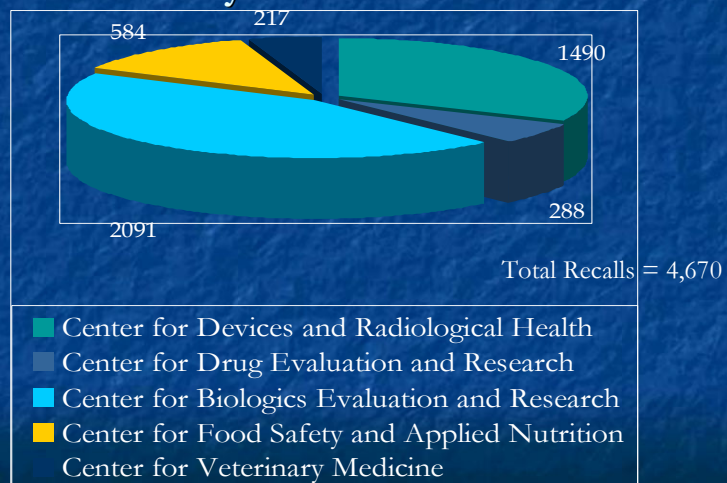


FDA Activities Report

ASQ
Midwest FDC Conference
November 4, 2005

Recalls for Fiscal Year 2004

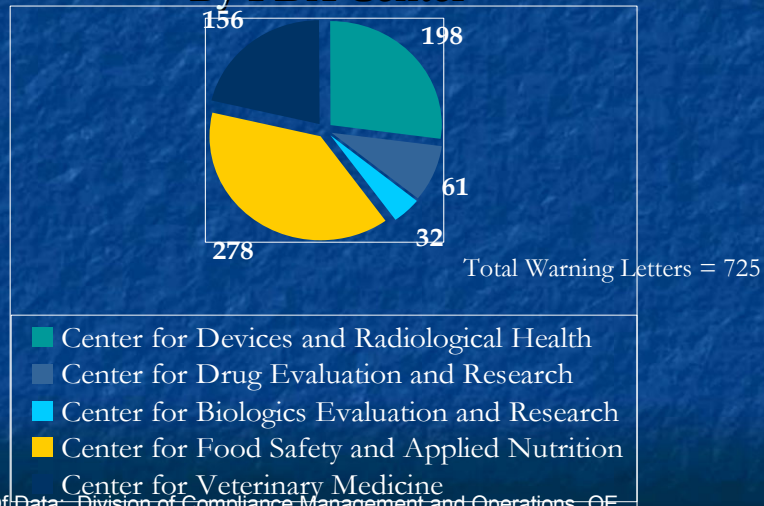
By FDA Center



Source Of Data: Division of Compliance Management and Operations, OE

Warning Letters for Fiscal Year 2004

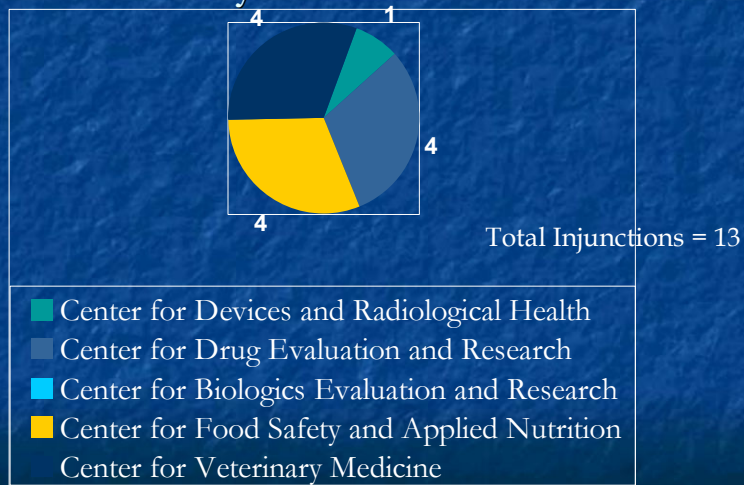
By FDA Center



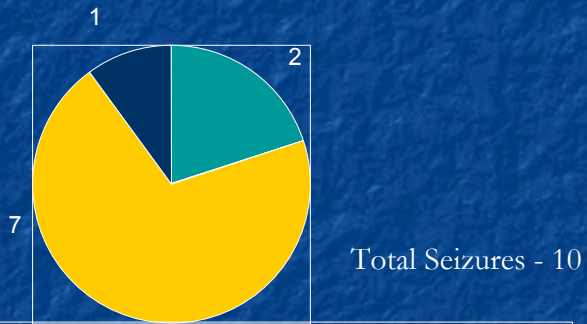
Source Of Data: Division of Compliance Management and Operations, OE
* 379 Warning Letters Issued through the 3rd Quarter of FY 2005

Injunctions for Fiscal Year 2004

By FDA Center



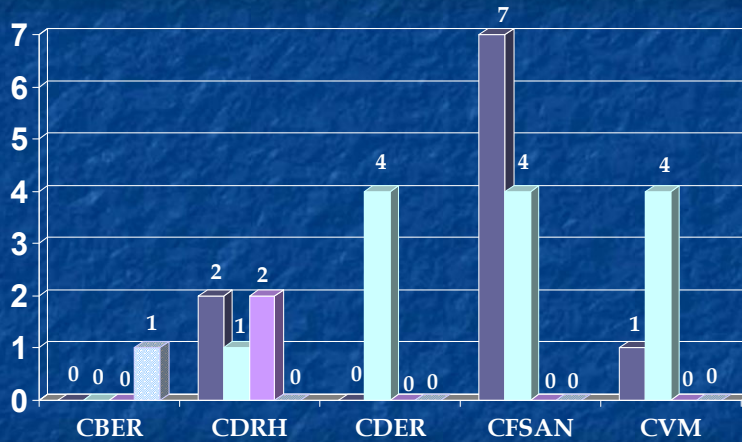
Seizures for Fiscal Year 2004 By FDA Center



- Center for Devices and Radiological Health
- Center for Drug Evaluation and Research
- Center for Biological Research and Evaluation
- Center for Food Safety and Applied Nutrition
- Center for Veterinary Medicine

Source Of Data: Division of Compliance Management and Operations, OE

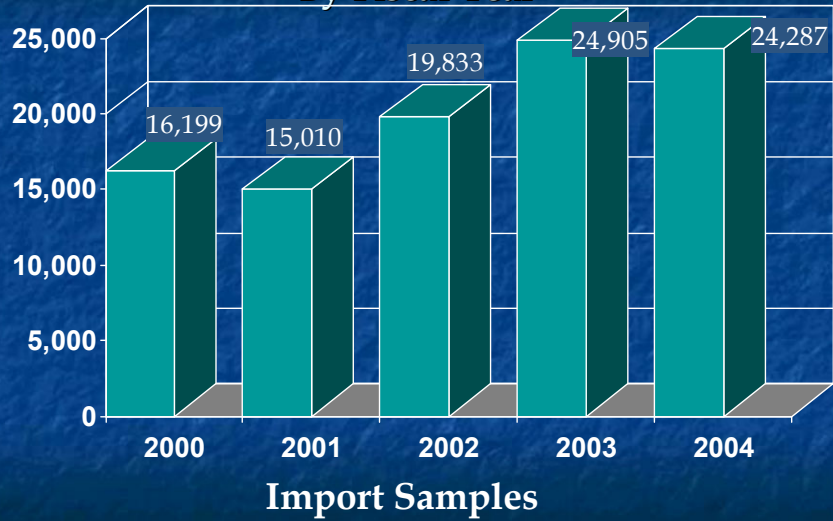
Enforcement Activities By Each FDA Center for Fiscal Year 2004



- Seizures = 10
- Injunctions = 13
- Civil Money Penalties = 2
- Clinical Investigator Disqualified = 1

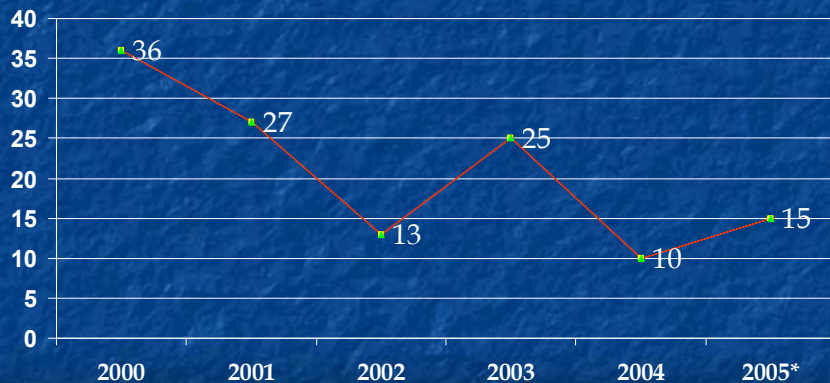
Source Of Data: Division of Compliance Management and Operations, OE

Surveillance Activity By Fiscal Year



Source of Data: Program Evaluation Branch, DPEM, Office of Resource Mgmt.

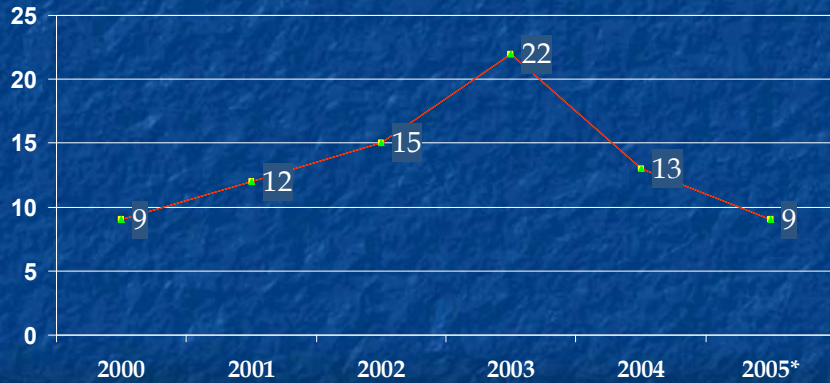
Seizures Fiscal Years 2000 – 2005*



Source Of Data: Division of Compliance Management and Operations, OE
* Through 3rd Quarter FY 2005

Injunctions Fiscal Years 2000 – 2005*

* Through 3rd Quarter FY 2005



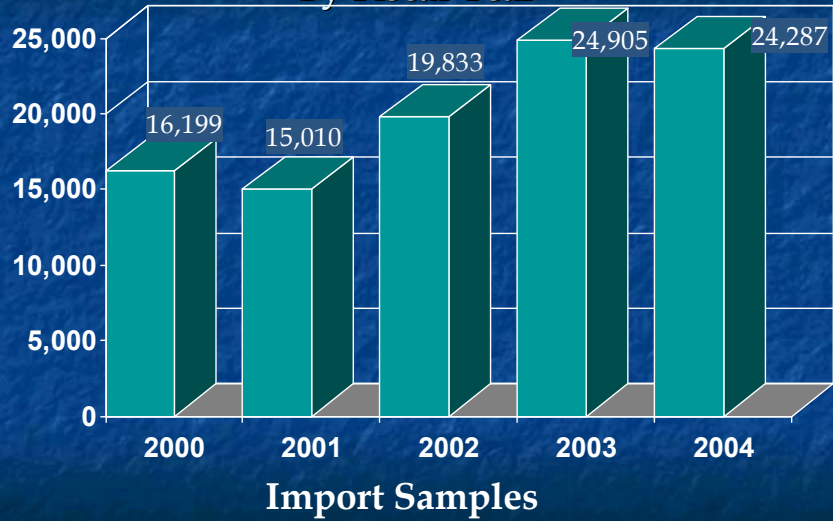
Surveillance Activity By Fiscal Year



Inspections: Domestic and Foreign

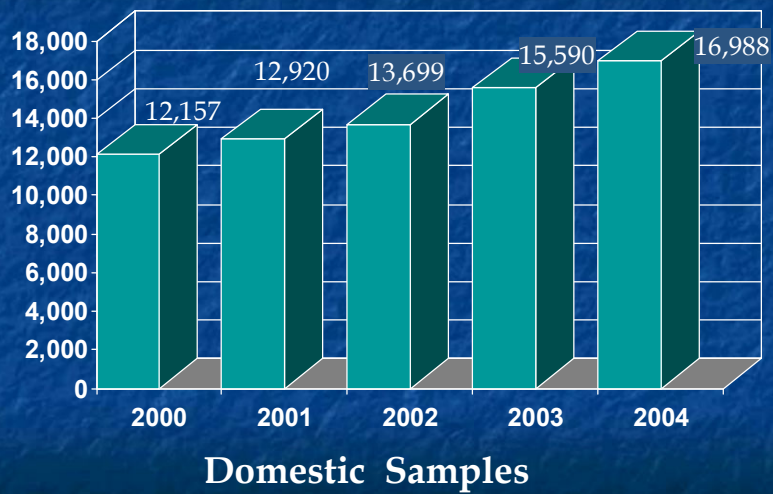
Source of Data: Program Evaluation Branch, DPEM, Office of Resource Mgmt.

Surveillance Activity By Fiscal Year



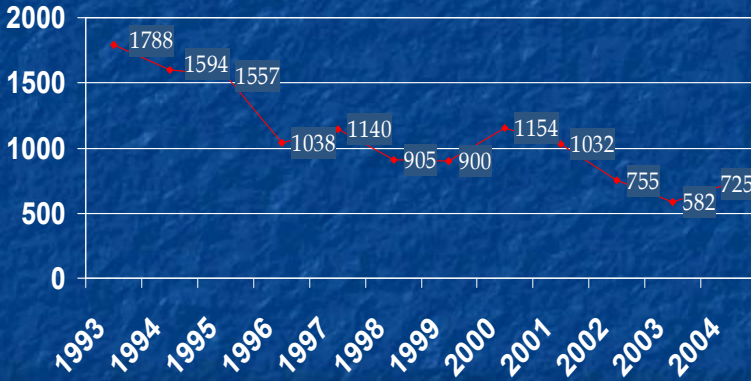
Source of Data: Program Evaluation Branch, DPEM, Office of Resource Mgmt.

Surveillance Activity By Fiscal Year



Source of Data: Program Evaluation Branch, DPEM, Office of Resource Mgmt.

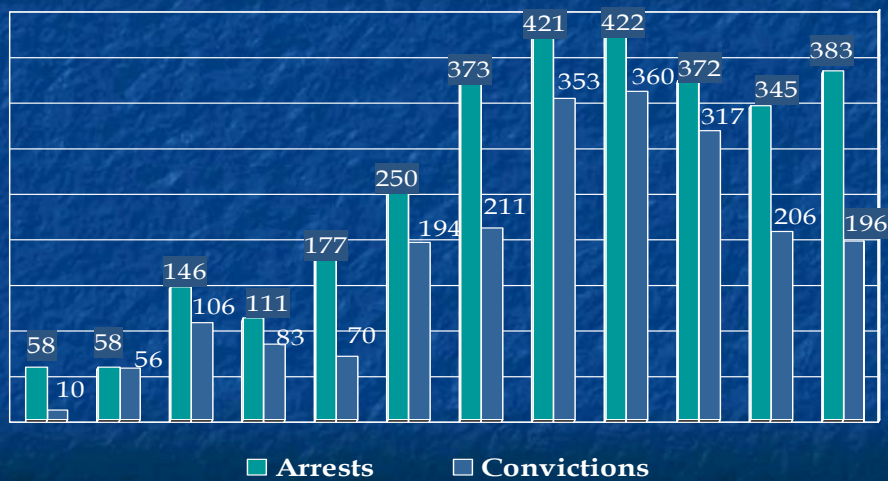
Warning Letters Fiscals Years 1993 - 2004



Recalls Fiscals Years 1994 - 2004



Office of Criminal Investigations Fiscal Years 1993 - 2004



Source of data: Office of Criminal Investigations, OE