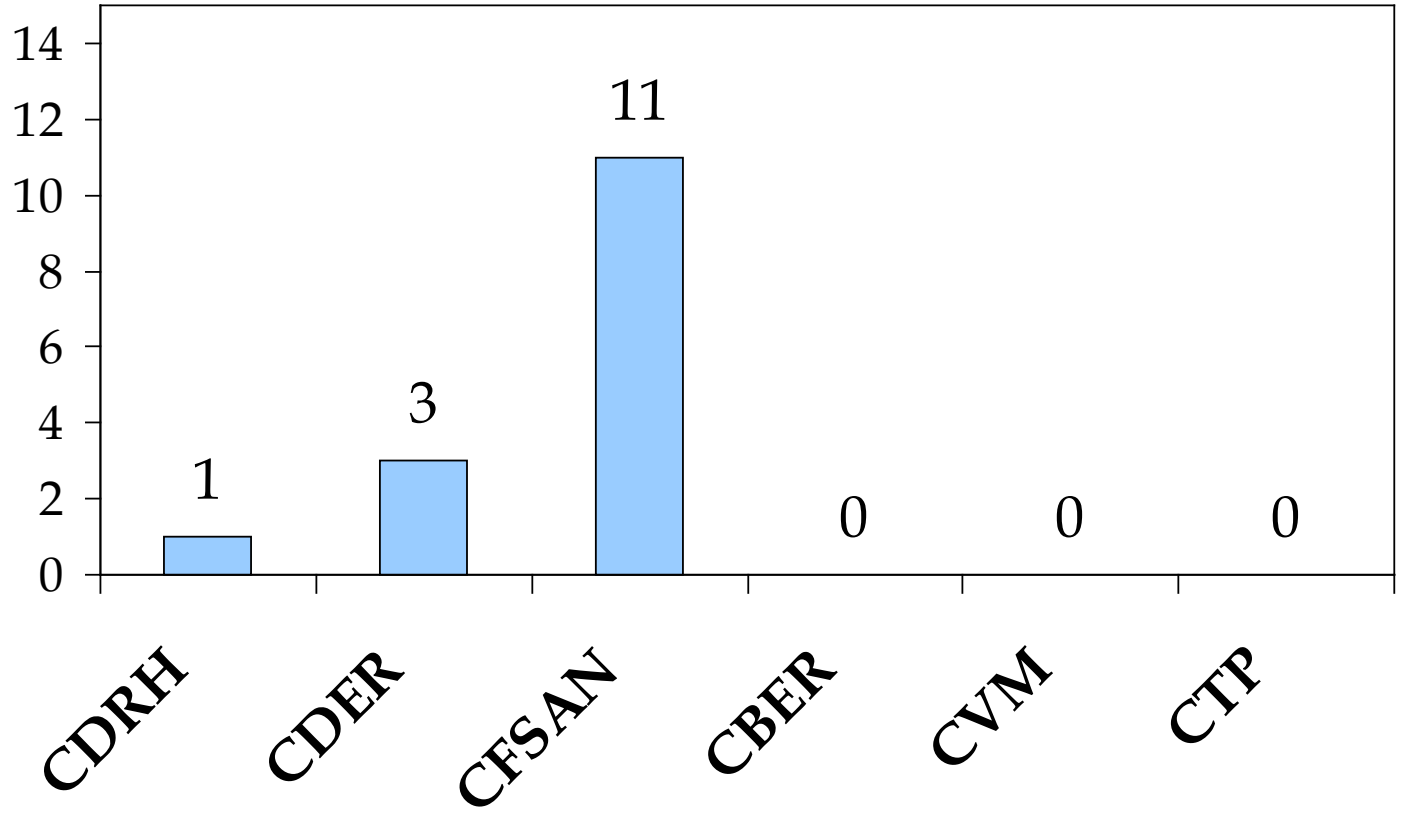
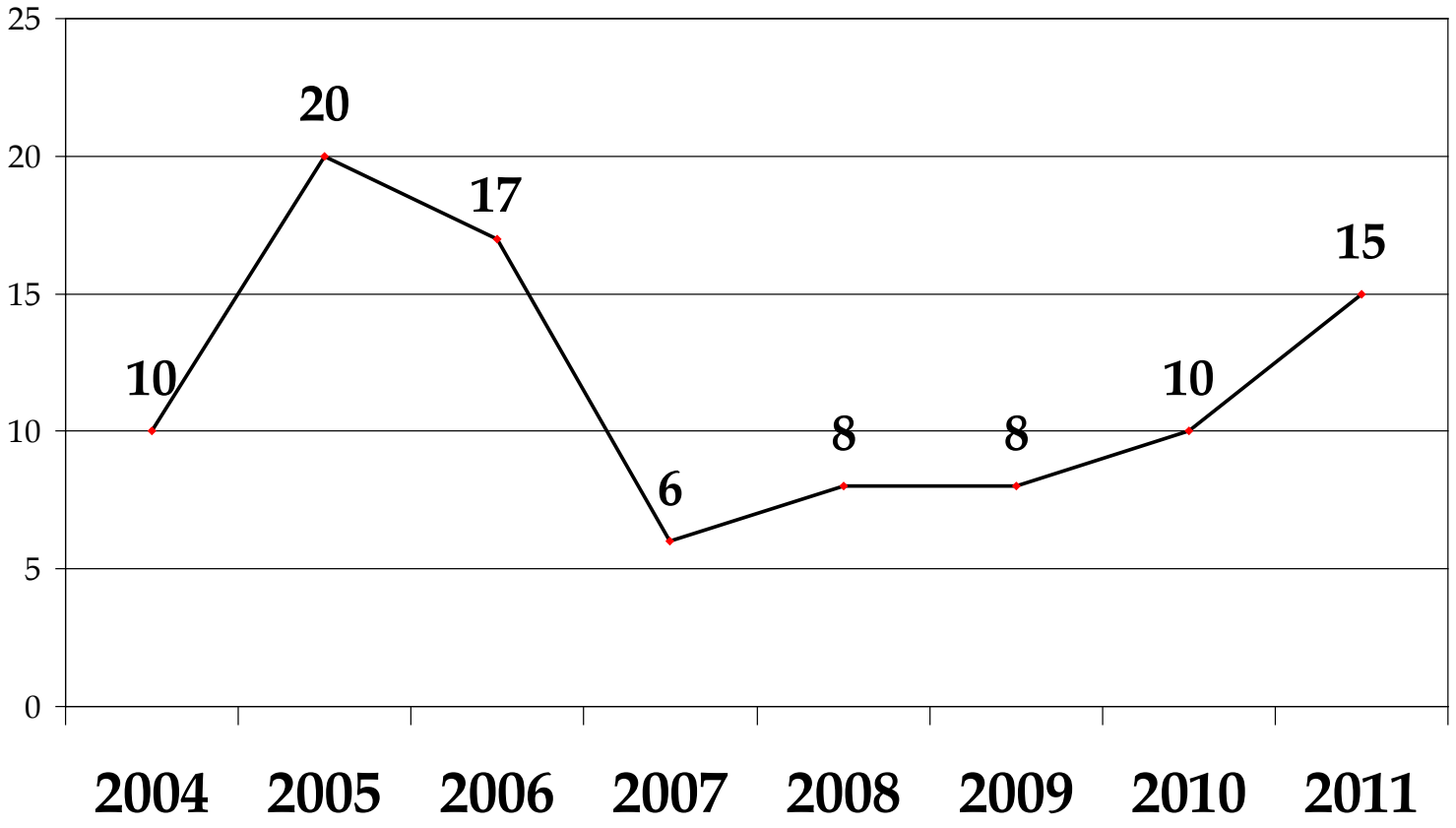
FDA Enforcement Statistics Summary Fiscal Year 2011

Seizures	15
Injunctions	16
Warning Letters	1,720
Recall Events	3,640
Recalled Products	9,288
Debarments	16

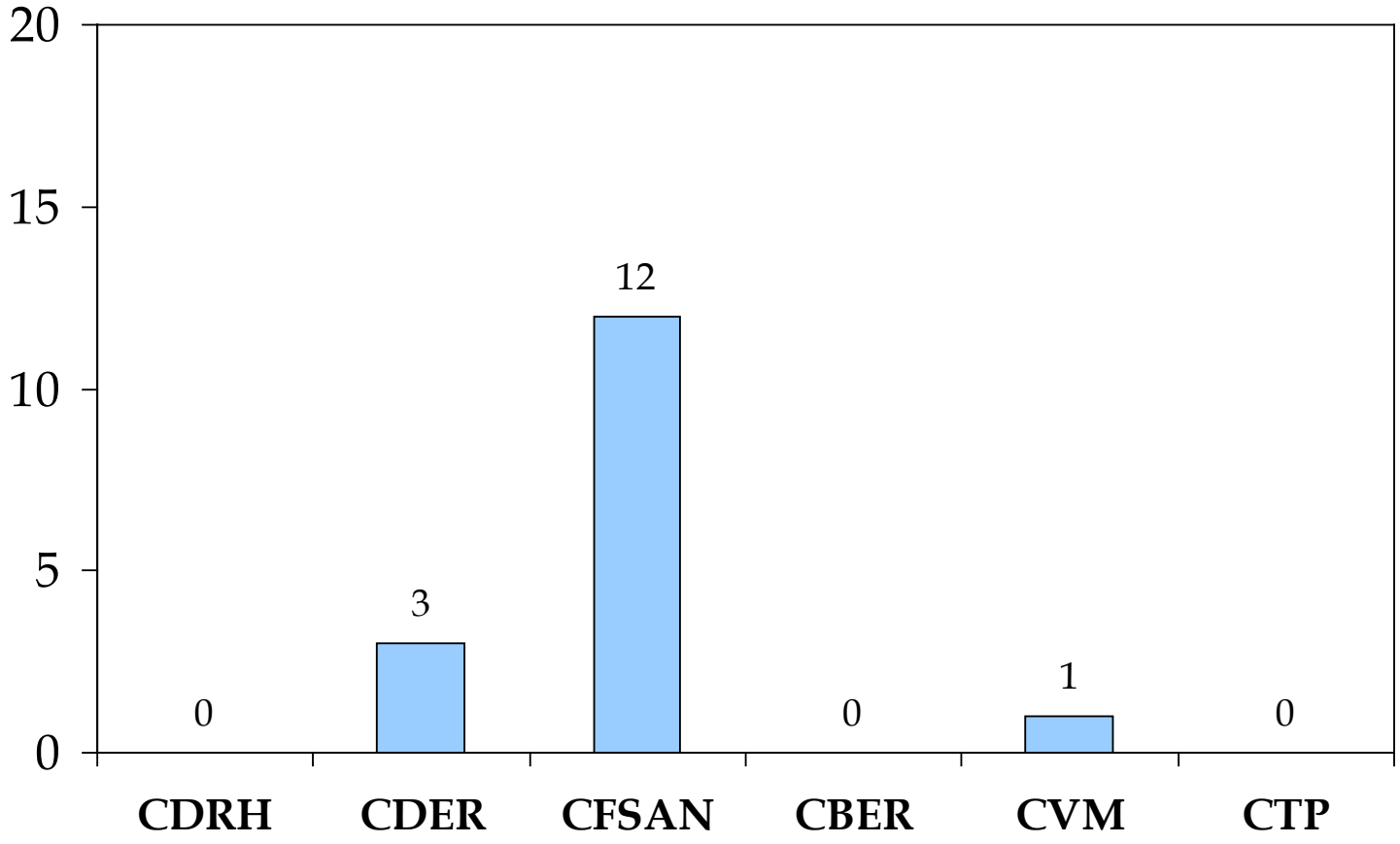
Seizures by FDA Center
Fiscal Year 2011



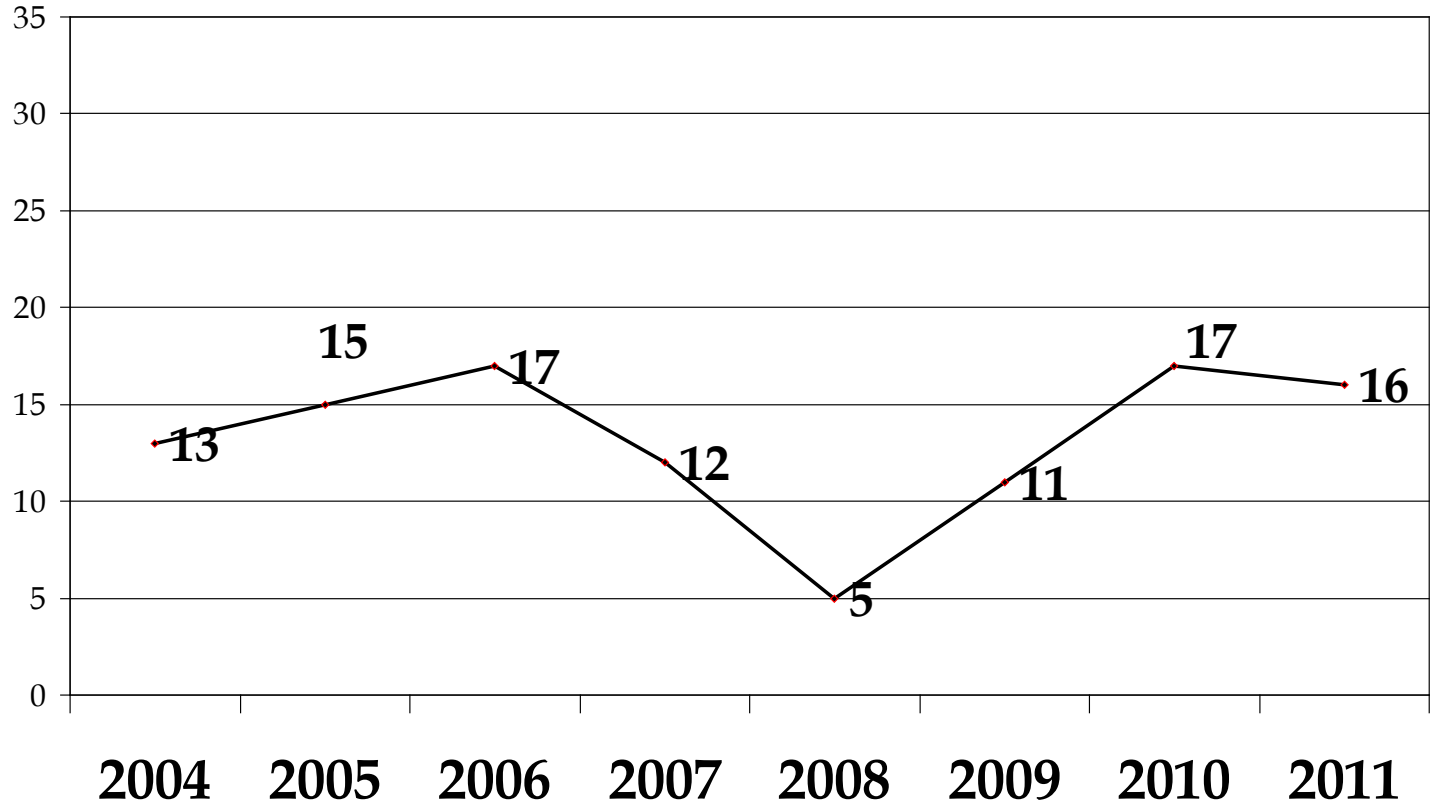
FDA Seizures
Fiscal Years 2004 – 2011



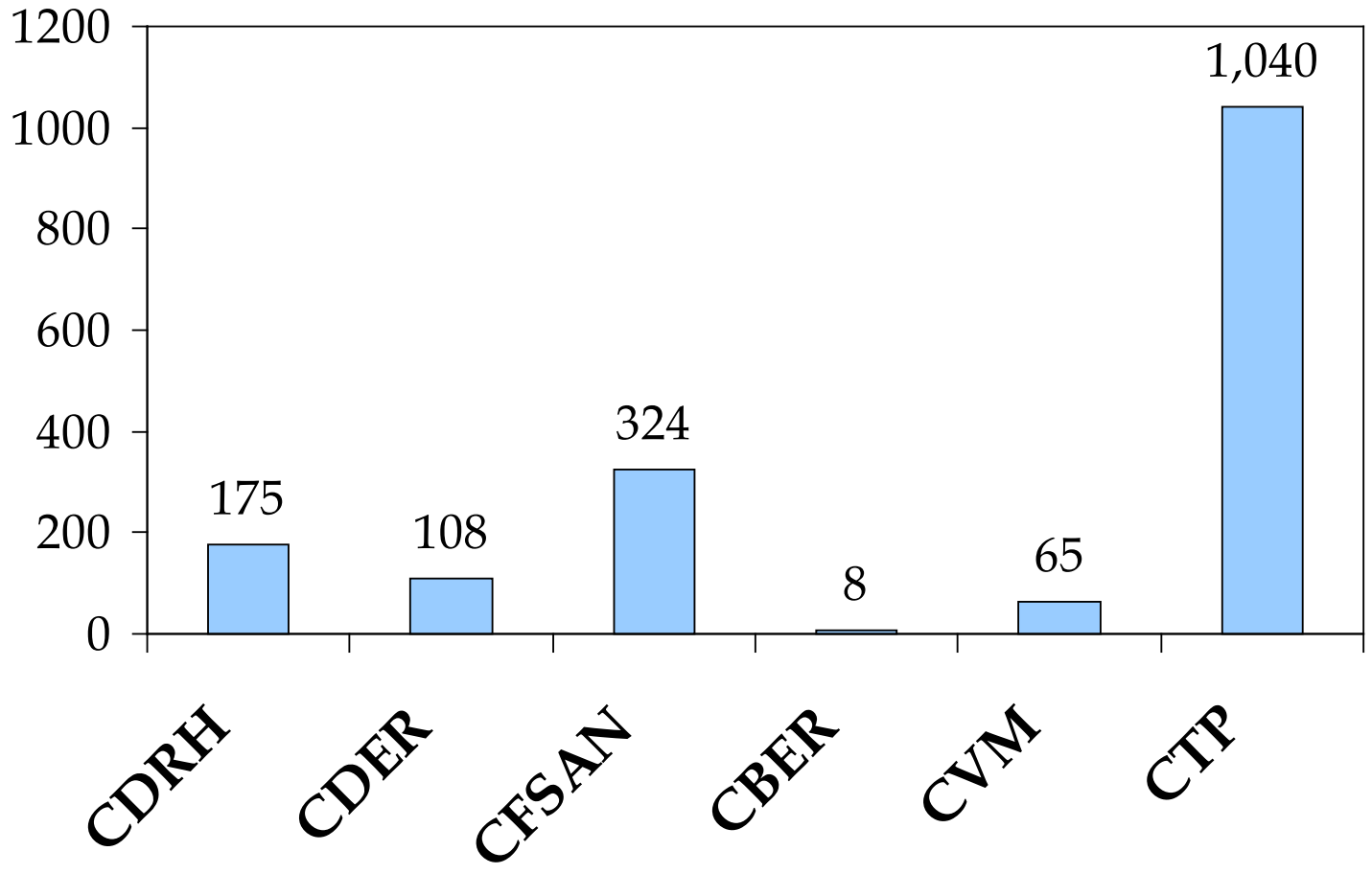
Injunctions by FDA Center
Fiscal Year 2011



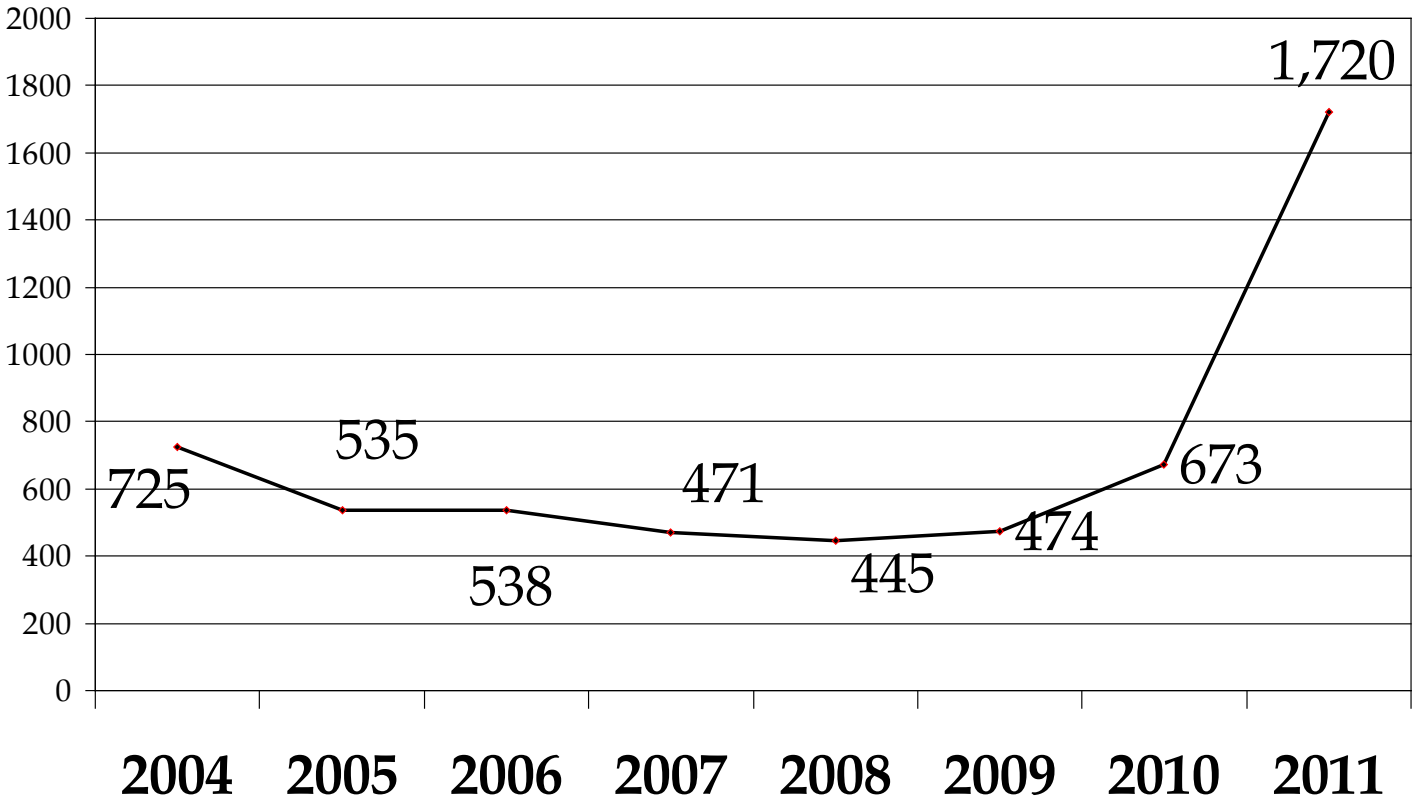
FDA Injunctions
Fiscal Years 2004 – 2011



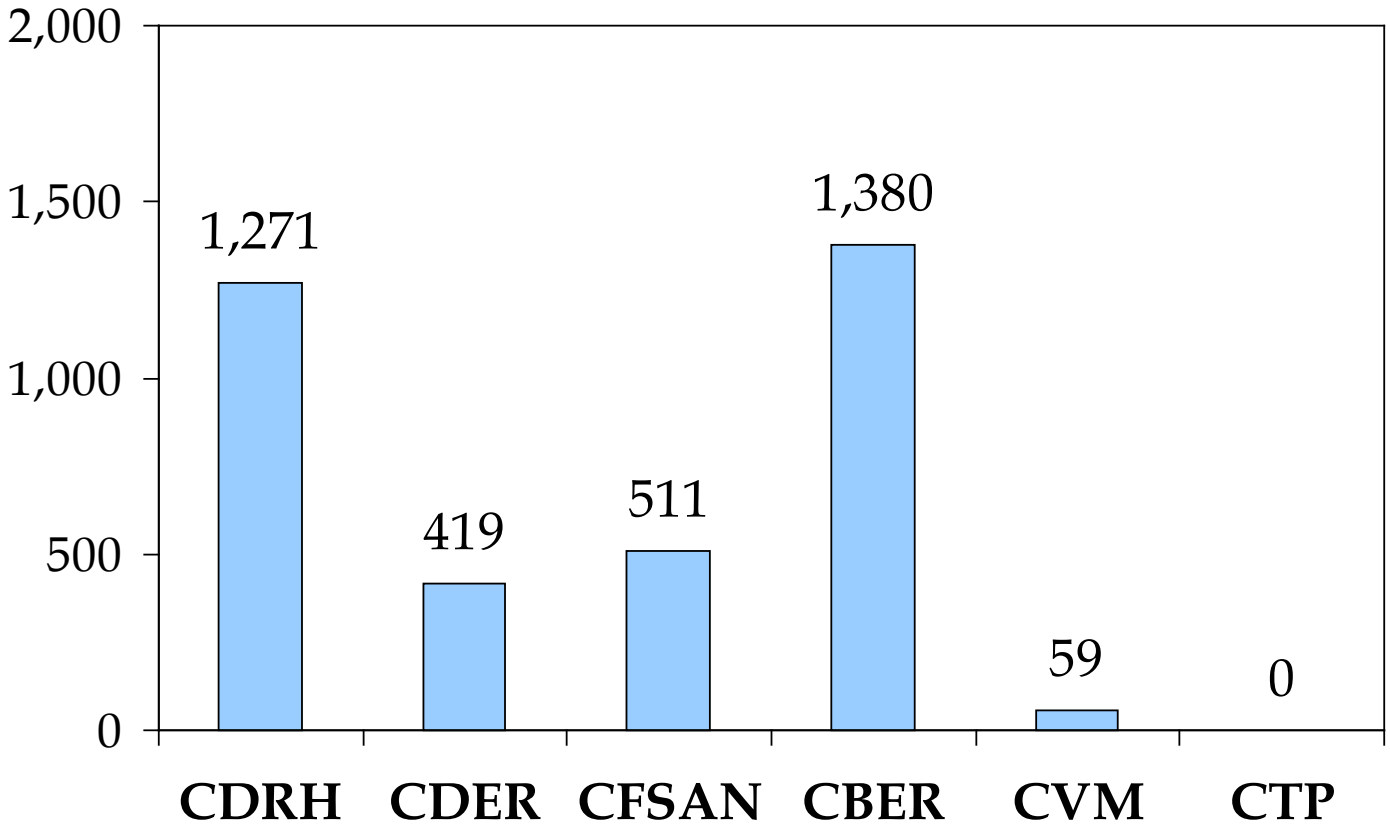
Warning Letters by FDA Center Fiscal Year 2011



FDA Warning Letters
Fiscal Years 2004 – 2011

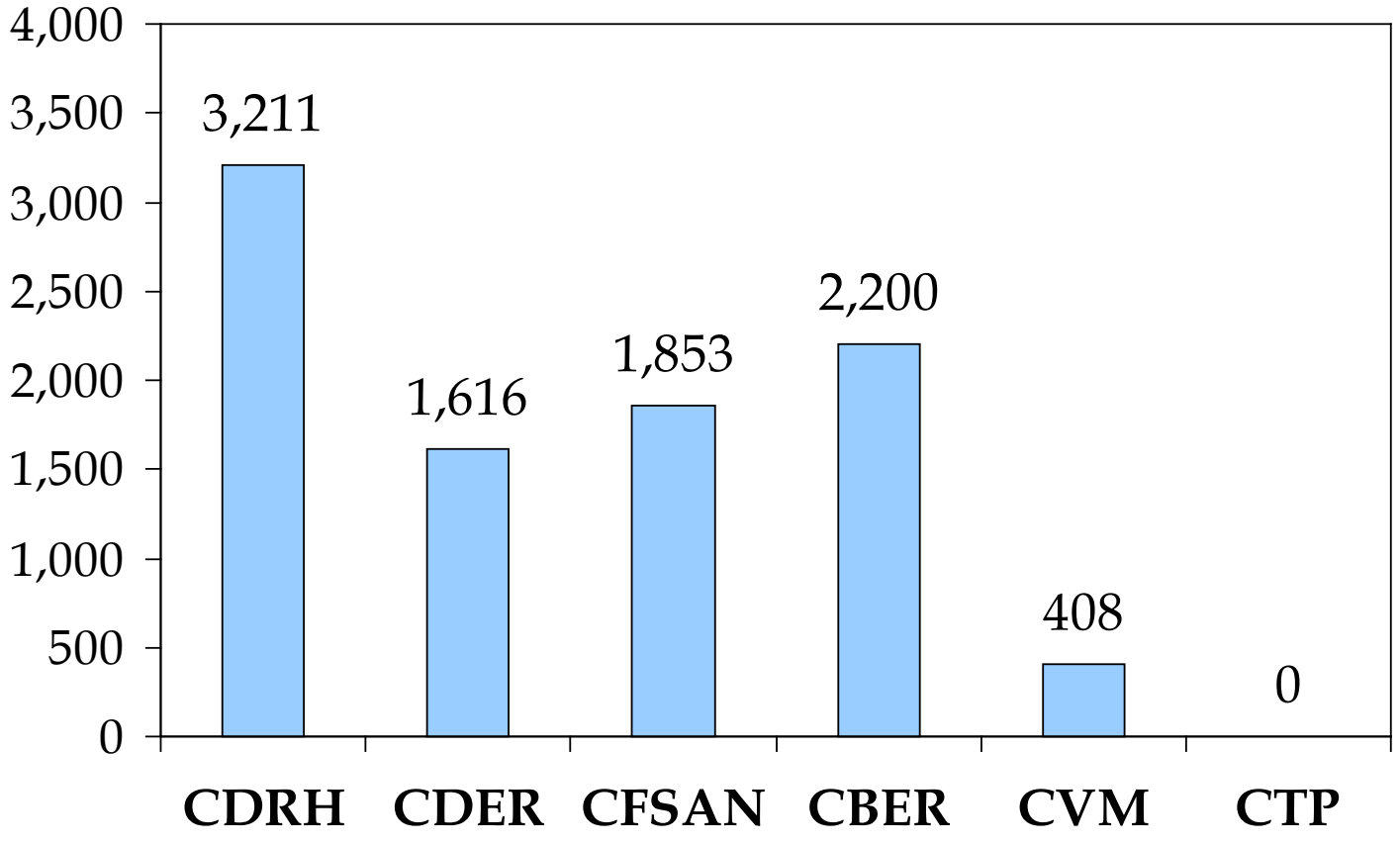


Total Recall Events by FDA Center
Fiscal Year 2011



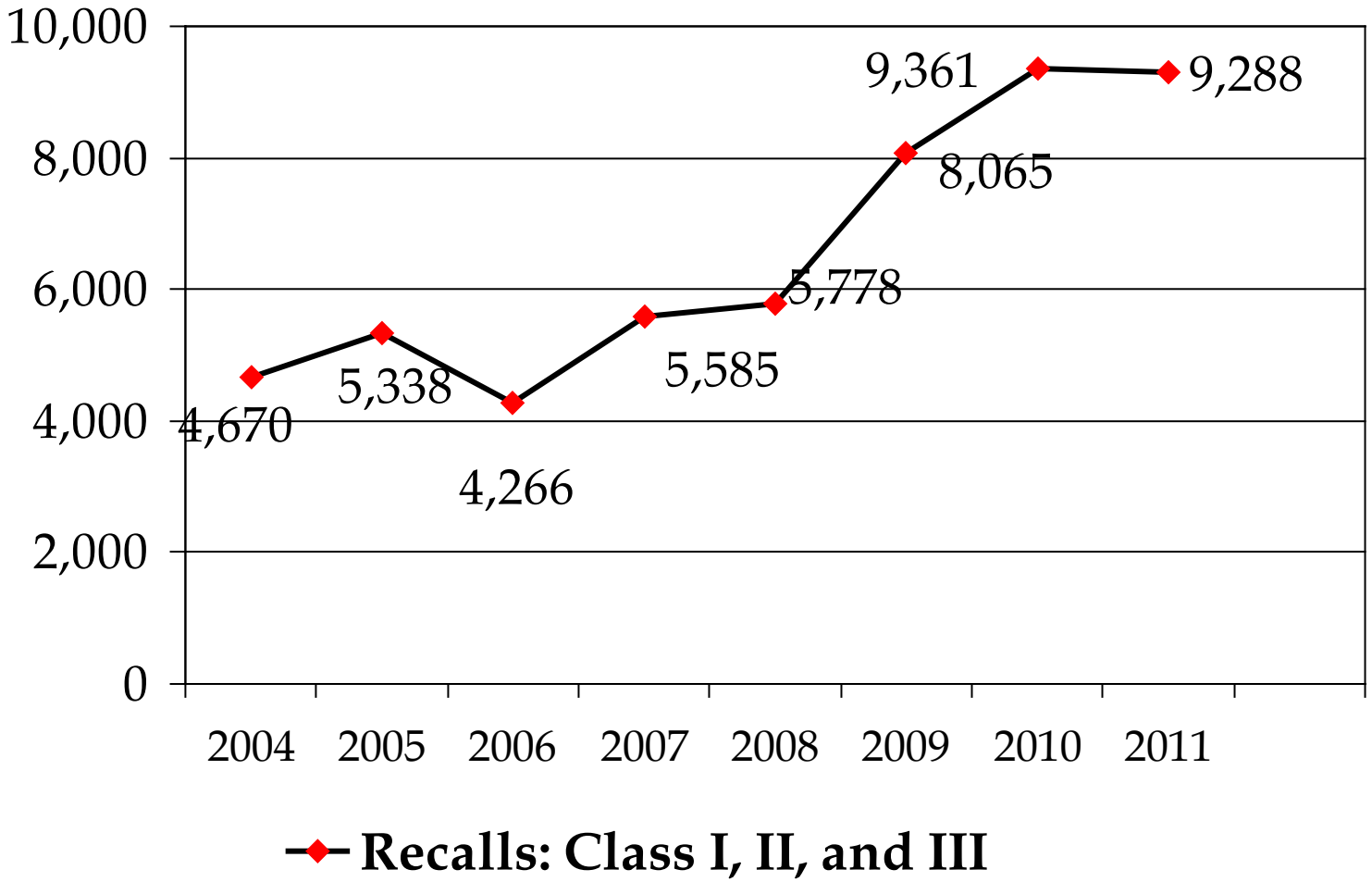
Class I, II and III

Total Recalled Products by FDA Center Fiscal Year 2011

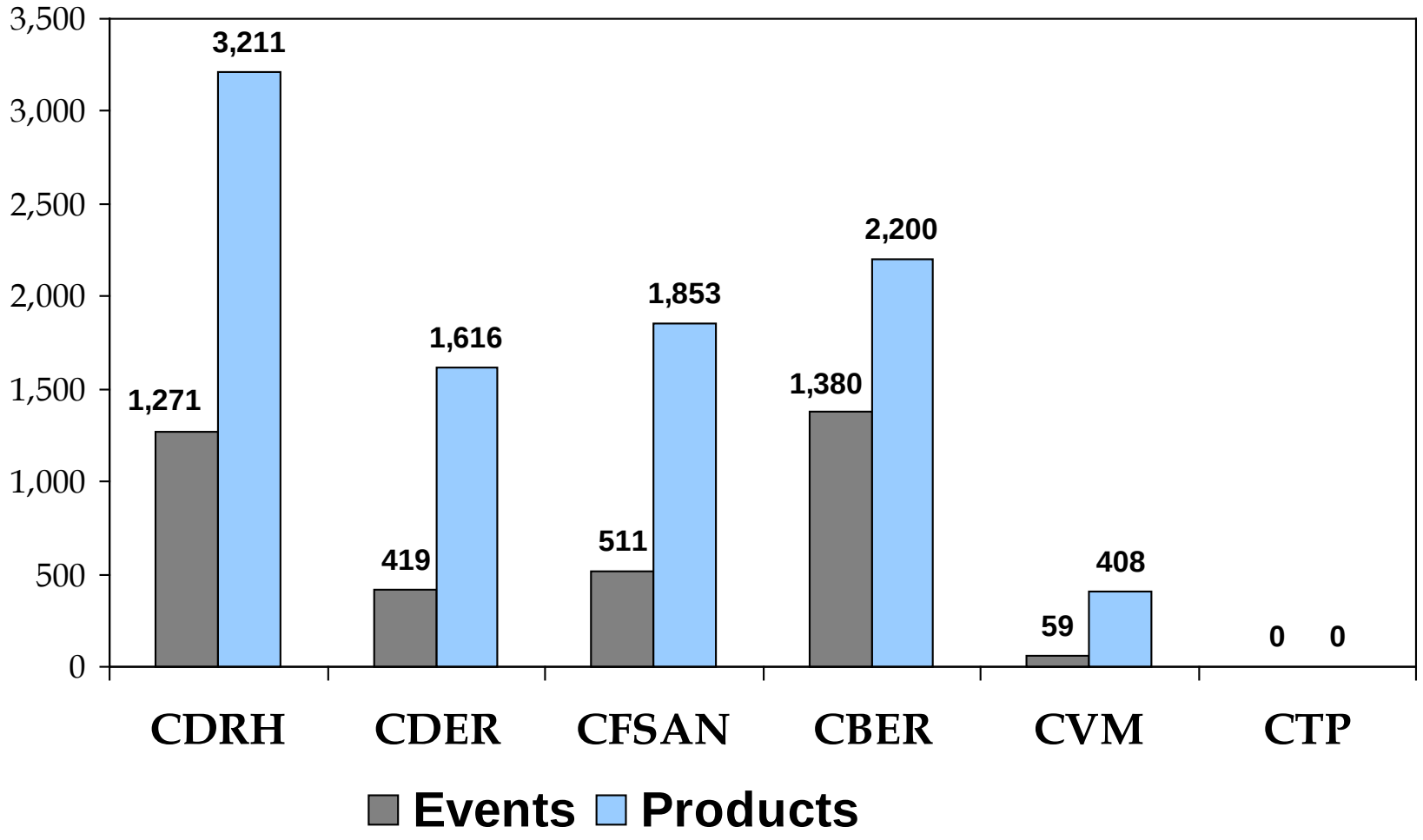


Class I, II and III

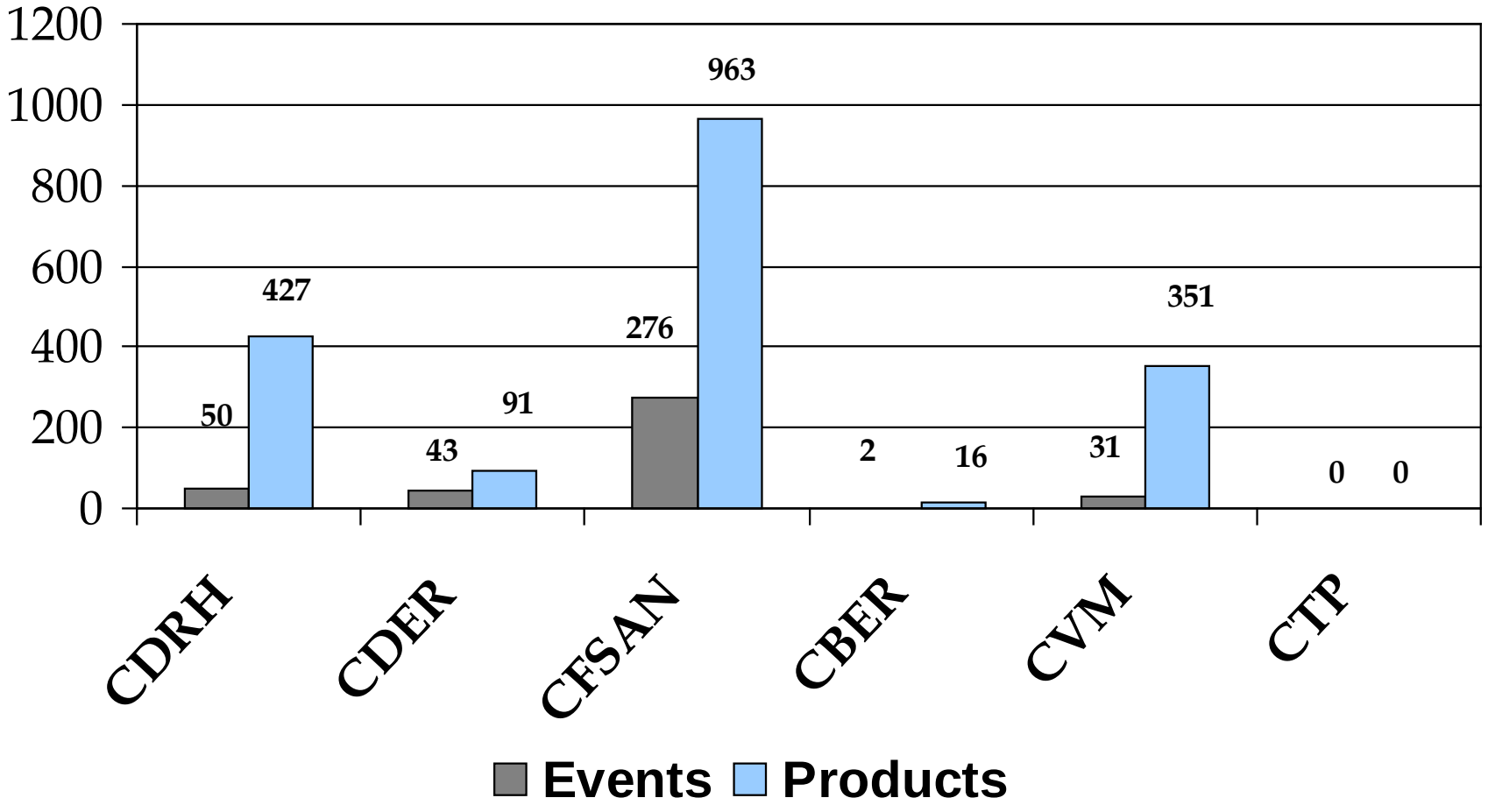
Recalled Products – All Centers
Fiscal Years 2004 – 2011



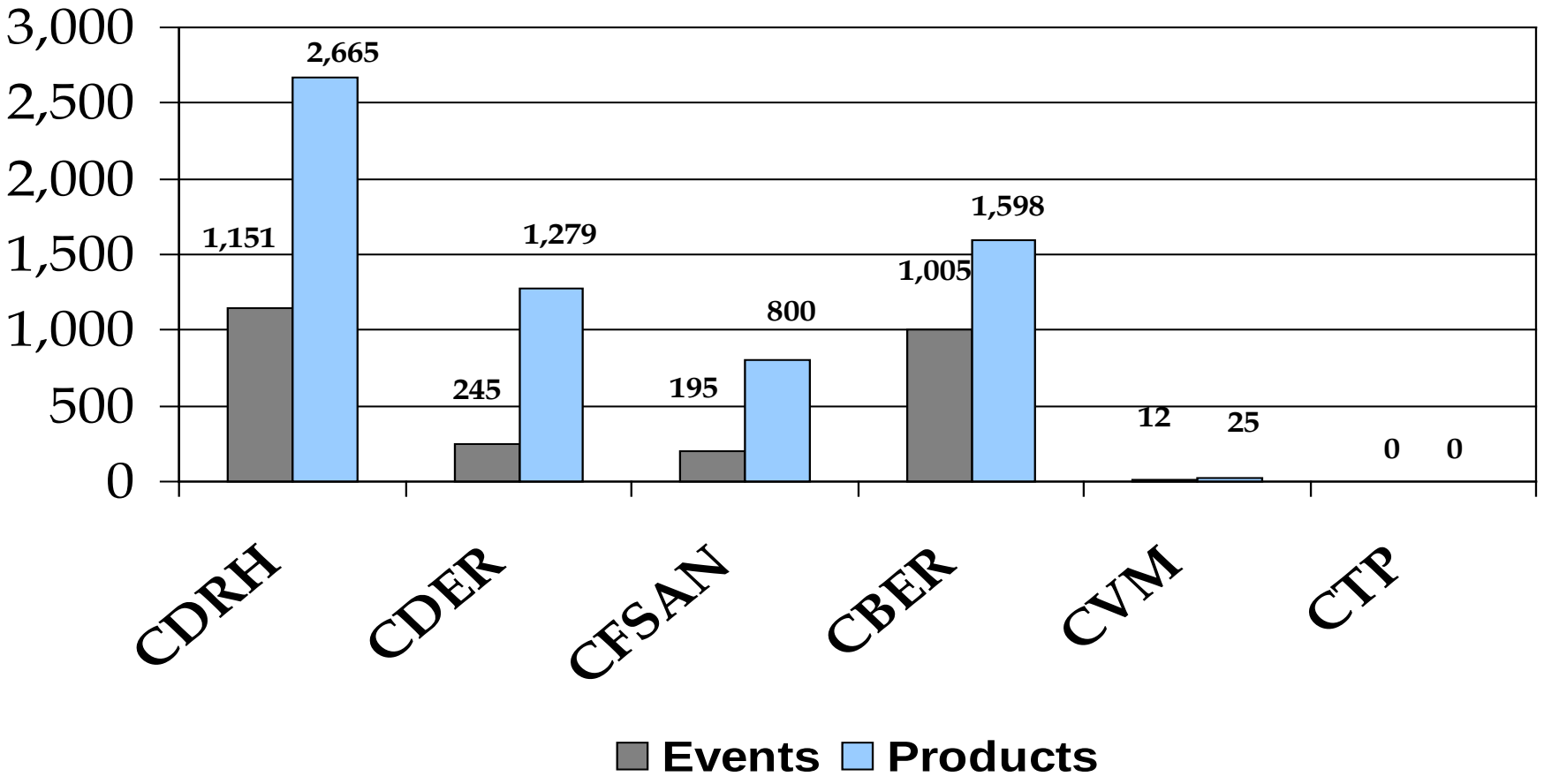
FDA Recalls By Center - All Classes Fiscal Year 2011



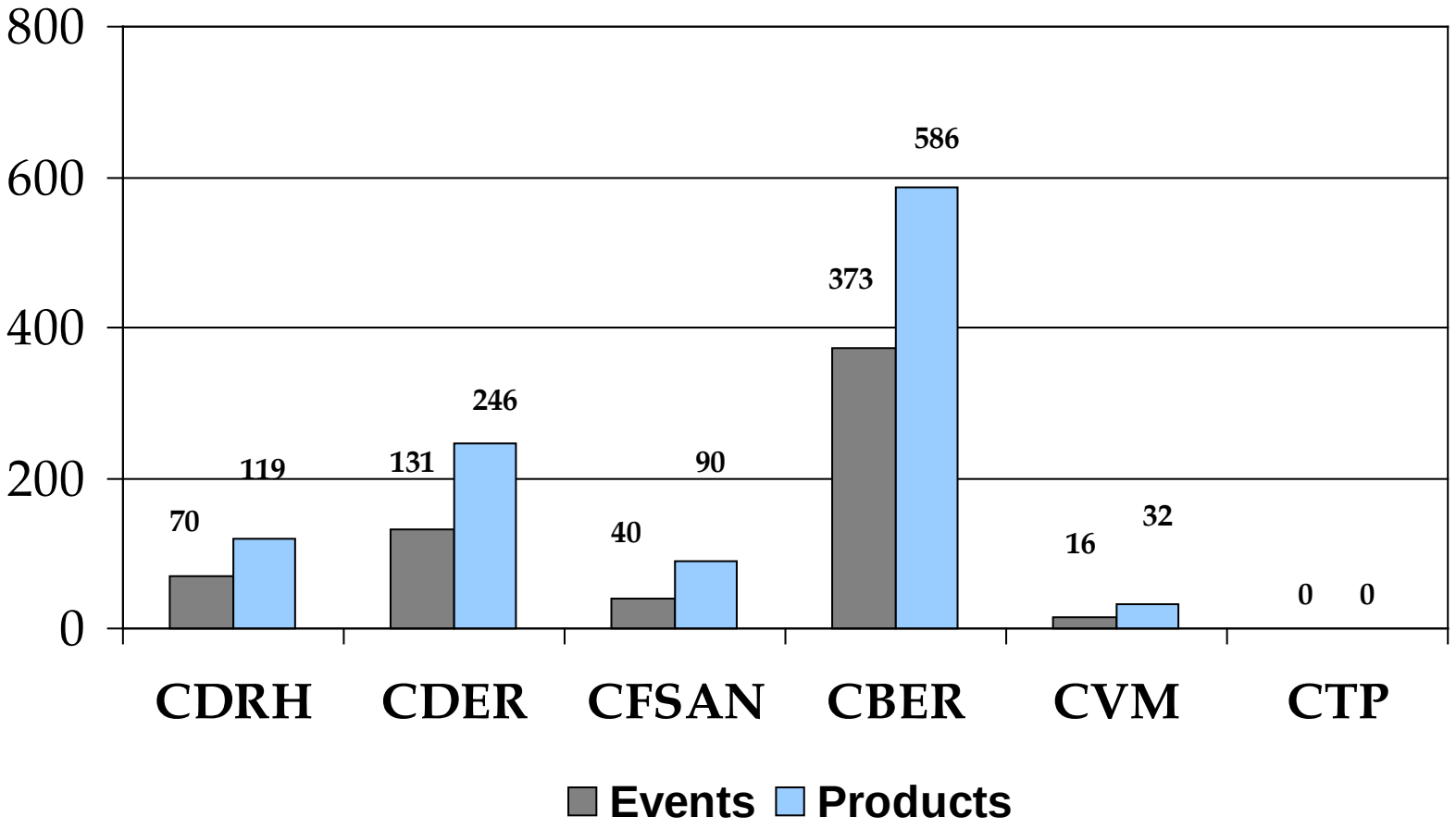
FDA Recalls – Class I By Center
Fiscal Year 2011



FDA Recalls - Class II By Center
Fiscal Year 2011



FDA Recalls - Class III By Center Fiscal Year 2011



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.