U.S. Food and Drug Administration

Drugs

Reports Received and Reports Entered into AERS by Year

(As of March 31, 2010)[1]

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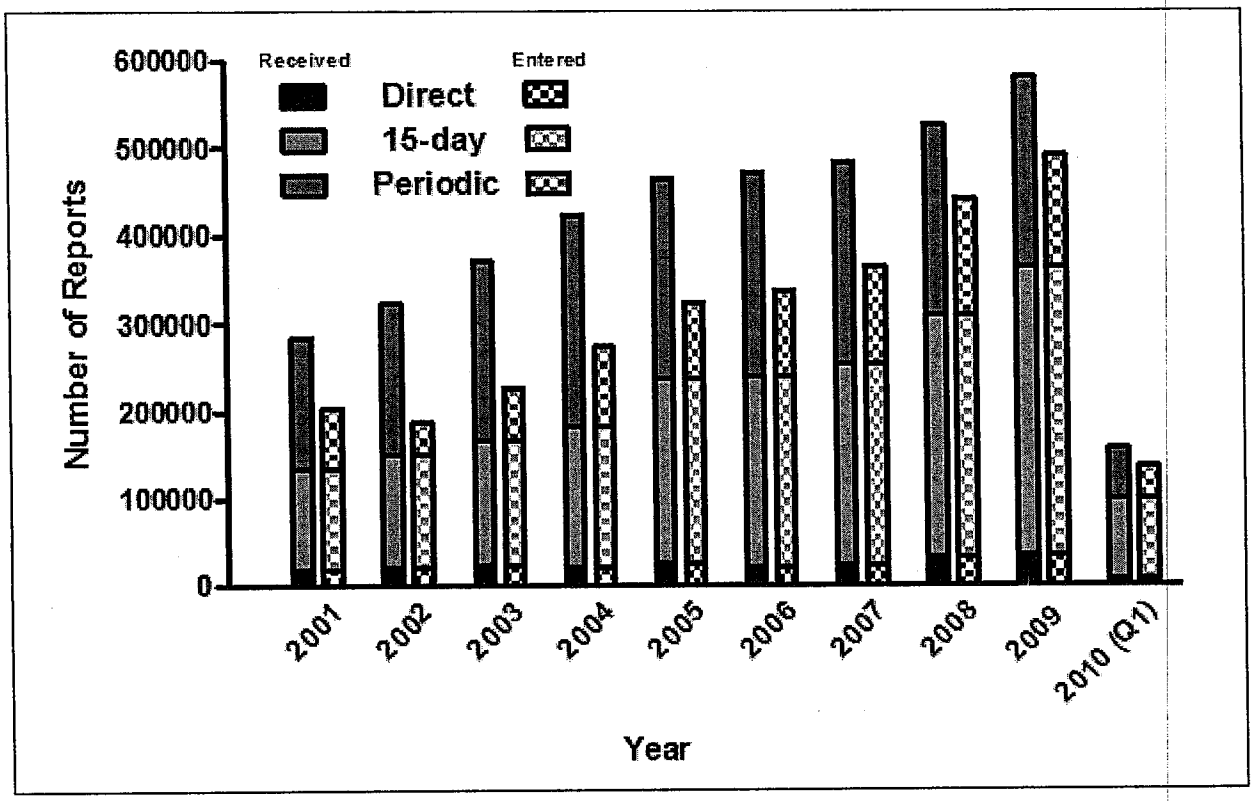
These data describe total numbers of reports received for drugs and therapeutic biologic products and the number of reports we entered into the AERS database. Not all of the reports that FDA receives for drug and therapeutic biologic products are entered into the AERS database. At the present time, we are entering reports of the following types:

- Reports submitted directly to FDA (not submitted through manufacturers)
- Reports submitted on 3500A (or CIOMS) forms by manufacturers that are categorized as:
  - 15-day reports
  - serious Periodic reports, or
  - nonserious Periodic reports for new molecular entity (NME) products within the first 3 years following FDA approval
- Reports submitted electronically by manufacturers regardless of category.

A manufacturer's 15-day report is a report that contains at least one event that is not currently described in the product labeling and the patient outcome is serious. A manufacturer's Periodic report is a report that did not meet the criteria for a 15-day report. Manufacturers submit Periodic reports to FDA quarterly for newer drugs (FDA-approved for three years or less) and annually for older drugs.

Figure 1. This figure illustrates the number of reports received (solid bars) and entered (checkered bars) into AERS by type of report since the year 2000 until the end of the first quarter of 2010.



This table represents the number of reports received by FDA and entered into AERS by type of report since the year 2000 until the end the third quarter of 2009.

Year	Direct	15-day	Periodic Received	Periodic Entered	Total Received	Total Entered
2000	16,131	94,931	155,804	89,290	266,866	200,352
2001	19,308	114,693	150,761	70,284	284,762	204,285
2002	20,438	128,680	173,375	36,924	322,493	186,042
2003	22,944	144,271	203,628	59,002	370,843	226,217
2004	21,655	162,007	239,268	89,939	422,930	273,601
2005	25,312	213,324	225,183	84,748	463,819	323,384
2006	20,977	219,956	230,461	96,222	471,394	337,155
2007	23,033	230,919	228,202	110,497	482,154	364,449
2008	32,899	275,421	218,207	133,047	526,527	441,367
2009	34,173	330,476	216,255	126,186	580,904	490,835
2010 (Q1)	8,177	91,459	57,411	36,599	157,077	136,235

Links on this page:

1. /Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm
2. /Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm