Two Ways to Research FDA Drug Adverse Events

Call FOI for a Custom Search

or

Use Dialog File 181

Since 1975, FOI Services has specialized in delivering unpublished U.S. Food and Drug Administration documents acquired using the Freedom of Information Act. To date, over 160,000 documents have been acquired, covering the full range of products regulated by the FDA, including medical devices and diagnostics, pharmaceuticals, biologics, veterinary products, and foods.

Here are just some of the types of FDA documents we have available:

Establishment Inspection Reports (EIRs) and 483s
FOI Services has thousands of EIRs summarizing results of inspections of clinical investigators and pharmaceutical and medical device manufacturers. When appropriate, these files include the Form FDA-483 recording negative observations.

Device Approvals
Over 39,000 device premarket notifications [510(k)s] and summaries of premarket approvals [PMAs] cover back to 1976 and the beginning of medical device regulation.

Drug Approvals
Summary Bases of Approval and/or FDA approval reviews are available for most FDA-approved pharmaceuticals.

Guidelines
Guidelines in the FOI Services collection include formal guidance documents as well as meeting papers, correspondence, and handbook chapters that have become *de facto* guidelines in the absence of more definitive guidance documents.

And lots more, including
Biologic Approvals, FDA/Industry Correspondence, Minutes of Meetings & Telephone Conversations, Speeches, Press Releases, Talk Papers, Warning Letters

Device Adverse Reaction Reports (MDRs)
While not available on the web, FOI can prepare custom reports of adverse reactions reported to FDA for medical devices. Call 301-975-9400 for details.

If you don't see the document you need on our web site, or would prefer to discuss your research needs with an information specialist, give us a call at 301-975-9400 — there's no charge for us to check our files for you. And if we don't have the document you need, we can place a custom document request to the FDA.

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ADR Brochure 7-2005.P65

FDA Drug Adverse Events

Since 1969, the FDA has legally mandated adverse drug reaction reports from pharmaceutical manufacturers and maintained them in their Adverse Drug Reactions (ADR) system. In November 1997 the ADR database was replaced by the Adverse Event Reporting System (AERS). AERS is maintained by MedWatch, the FDA's Safety Information and Adverse Events Reporting Program.

FOI Services offers you quick access to all of these reports – you can search them yourself or have us perform the search for you.

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Dialog File 181. DIOGENES: Adverse Drug Events

If you're a Dialog searcher, take advantage of File 181, which contains the text of adverse drug event description back to 1969. An invaluable resource for competitive intelligence researchers, quality control and quality assurance specialists, drug safety officers, information specialists and more, DIOGENES: Adverse Drug Events lets you target just the drugs you need to see.

For search hints, see the Dialog's online story at:
support.dialog.com/publications/chronolog/200401/1040135.shtml

Sample record from Dialog File 181:

DIALOG(R)File 181:DIOGENES(R) Adverse Drug Events Database
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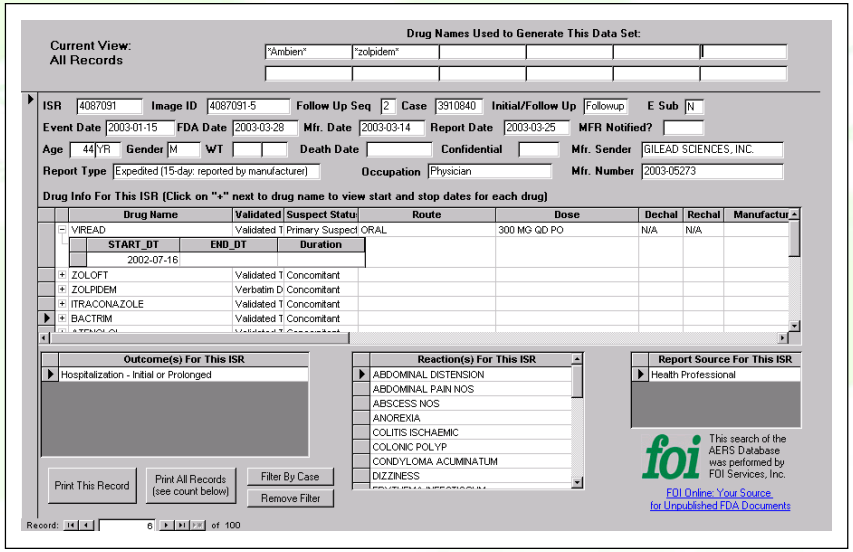
0002658586
FDA Report number: 3641049
Report type: AER
FDA Receipt Date: January 2, 2001
Report Title:
AERS Drug Report. 6 Suspect Drug(s): Cytosar-U, Homoharringtonine (Homoharringtonine), Hydrea, Lasix (Furosemide), Omeprazole, Zelitrex (Valaciclovir). Total 6 Drug(s) Cited.
Sending Manufacturer: Pharmacia And Upjohn Co
Report Code: Expedited (15-day: reported by manufacturer)
Report Source: Foreign; Health Professional; Other
Source/update date: FDA AERS list (20030821)
Manufacture Report#: 2000038463FR
FDA Request number: 3641049-6
Reaction Date: October 27, 2000
Reactions: Cardiac Arrest Klebsiella Infection NOS Proteus Infection NOS
Pseudomonas Aeruginosa Infection NOS Respiratory Distress
Staphylococcal Infection NOS Streptococcal Infection NOS
Outcomes: Death
Patient Information:
Age: 62 Years
Sex: Male
Drug Information:
Primary Suspect: Cytosar-U; Manufacturer Reported: Unknown; Dosage Reported: 10 MG, CYCLIC, SUBCUTANEOUS; Reported Route: SUBCUTANEOUS; N/A Dechallenge Result; N/A Rechallenge Result; Validated Trade Name; Drug Name Source; Unknown Lot Number; Unknown Expiration; Therapy Dates
(Start-End): 20001016-20001020
Secondary Suspect: Homoharringtonine (Homoharringtonine); Manufacturer Reported: Unknown; Dosage Reported: CYCLIC, IV; Reported Route: INTRAVENOUS; N/A Dechallenge Result; N/A Rechallenge Result; Verbatim Drug Name Drug Name Source; Unknown Lot Number; Unknown Expiration; Therapy Dates (Start-End): 20001016-20001022
Secondary Suspect: Hydrea; Manufacturer Reported: Unknown; Dosage Reported: 2500 MG, ORAL; Reported Route: ORAL; N/A Dechallenge Result; N/A Rechallenge Result; Validated Trade Name Drug Name Source; Unknown Lot Number; Unknown Expiration; Therapy Dates (Start-End): 20000926-20001027

record continues.....

FOI's Custom Adverse Event Searches

If you prefer we do your Adverse Events search, just call or email us with the name(s) of the drug(s) you're researching. We'll provide a custom Microsoft Access database of the adverse event files, allowing you to examine individual events or prepare specialized reports. Download a free sample search at our website at *www.foiservices.com/aers* , email *infofoi@foiservices.com* or call 301-975-9400 to take a look at all these features:

- **View all records in which the searched drug appears**
- **View records where the searched drug has primary or secondary status**
- **View results by reaction**
- **Easy-to-read summaries of outcomes and reactions**
- **Export underlying tables to perform your own analyses**
- **Fast turnaround time, with overnight or electronic delivery included**
- **Arrange for your search by calling 301-975-9400 or emailing *infofoi@foiservices.com***



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