An eventful year for the FDA

With a seemingly endless string of scandals, 2007 turned out to be a tough year for the US Food and Drug Administration (FDA). Things turned around in September, when Congress gave the FDA new powers to monitor drug safety, but here's a quick sampling of the beleaguered agency's many troubles:

Dec 23

Only 24% of drugs approved by the FDA between 2000 and 2006 were evaluated by an advisory panel, the Washington, DC–based group Public Citizen reports (*Lancet* **368**, 2210).

Jan 4

The FDA approved only 17 drugs in 2006, the lowest number in a decade, and each drug cost an average of $1.5 billion to develop, according to a Tufts University study.

Jan 30

The agency unveils a 38-page proposal to enhance drug safety, including a pilot project to assess the safety of approved drugs.

Feb 12

The FDA slaps a 'black-box' warning on the antibiotic Ketek, linked to liver failure and death, and restricts its use to cases of pneumonia one day before a congressional hearing on drug safety.

Mar 9

The FDA issues strict warnings for three anemia drugs linked to heart attack and blood clots in individuals with chronic kidney failure and to rapid tumor growth in those with cancer.

Mar 16

The FDA decides to fully fund its Office of Women's Health less than a month after intense criticism over its plans to cut $1.2 million from the office's $4 million budget.

May 21

A meta-analysis of 42 clinical trials, based in part on data reported to the FDA in 2006, finds that individuals taking GlaxoSmithKline's diabetes drug Avandia have a 43% increased risk of heart attack (*N. Engl. J. Med.* **356**, 2457–2471).

June 4

The FDA announces plans to appoint a 15-member advisory committee of ethicists, journalists, marketing specialists and other experts to help communicate drug safety information to consumers.

Aug 14

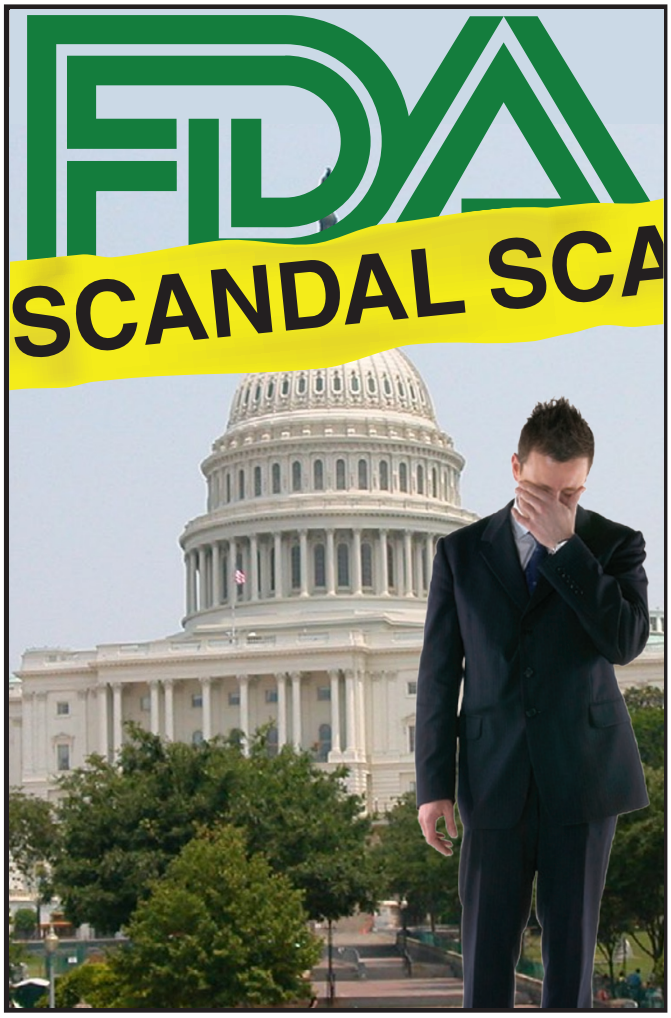
The makers of Avandia and Actos agree to issue black-box warnings about the drugs' association with heart failure two months after a House committee chastises the FDA on the matter.

Aug 15

The FDA warns parents that cough and cold medicines can be dangerous for young children, seven months after a report says that the drugs sent more than 1,500 children to the emergency room over two years.

Aug 27

Two members of Congress rebuke the FDA for considering a plan to outsource more than 300 jobs.



Sept 11

Reports of deaths and serious injuries caused by prescription and over-the-counter medicines nearly tripled between 1998 and 2005, researchers report (*Arch. Intern. Med.* **167**, 1752–1759).

Sept 18

The FDA launches a drug safety newsletter for healthcare professionals, fulfilling an Institute of Medicine recommendation to improve communication released a year earlier.

Sept 27

President Bush signs a law directing drug makers to post the results of their clinical trials in a public database and giving the FDA more power to demand post-marketing safety studies.

Nov 1

The FDA cannot guarantee the safety of the nation's drug supply because the agency inspects few foreign drug manufacturing facilities and lacks an accurate list of which facilities are subject to inspection, according to the US Government Accountability Office.