

FDA AGENCY REPORT – SEPTEMBER 2011

Here is a summary of recent product safety, product approvals and announcements to keep you informed about FDA issues. A brief summary of each issue and a web link to detailed information on the FDA website is included.

PRODUCT SAFETY:

[Abnormal heart rhythms associated with high doses of Celexa \(citalopram hydrobromide\)](#)
(Aug 24)

FDA is informing healthcare professionals and patients that the antidepressant Celexa (citalopram hydrobromide) should no longer be used at doses greater than 40 mg per day because it can cause abnormal changes in the electrical activity of the heart. Studies did not show a benefit in the treatment of depression at doses higher than 40 mg per day.

[Safety review update of Recombinant Human Growth Hormone \(somatropin\) and possible increased risk of death](#) (Aug 4)

FDA is updating the public about its ongoing safety review of recombinant human growth hormone (somatropin) and possible increased risk of death. FDA has determined that, at this time, the evidence regarding recombinant human growth hormone and increased risk of death is inconclusive.

[Updated drug labels for pioglitazone-containing medicines](#) (Aug 4)

FDA has approved updated drug labels for the pioglitazone-containing medicines to include safety information that the use of pioglitazone for more than one year may be associated with an increased risk of bladder cancer.

[Use of long-term, high-dose Diflucan \(fluconazole\) during pregnancy may be associated with birth defects in infants](#) (Aug 3)

FDA is informing the public that chronic, high doses (400-800 mg/day) of the antifungal drug Diflucan (fluconazole) may be associated with a rare and distinct set of birth defects in infants whose mothers were treated with the drug during the first trimester of pregnancy. This risk does not appear to be associated with a single, low dose of fluconazole 150 mg to treat vaginal yeast infection.

For more product safety information, please visit our [MedWatch](#) website.

PRODUCT APPROVALS:

[FDA approves Xalkori with companion diagnostic for a type of late-stage lung cancer](#)
(Aug 26)

FDA approved Xalkori (crizotinib) to treat certain patients with late-stage, non-small cell lung cancers who express the abnormal anaplastic lymphoma kinase gene.

[FDA approves Firazyr to treat acute attacks of hereditary angioedema](#) (Aug 25)

FDA approved Firazyr (icatibant) Injection for the treatment of acute attacks of a rare condition called hereditary angioedema in people ages 18 years and older.

[FDA approves Botox to treat specific form of urinary incontinence](#) (Aug 25)

FDA approved Botox (onabotulinumtoxinA) injection to treat urinary incontinence in people with neurologic conditions such as spinal cord injury and multiple sclerosis who have overactivity of the bladder.

[FDA approves Adcetris to treat two types of lymphoma](#) (Aug 19)

FDA approved Adcetris (brentuximab vedotin) to treat Hodgkin lymphoma and a rare lymphoma known as systemic anaplastic large cell lymphoma.

[FDA approves Zelboraf and companion diagnostic test for late-stage skin cancer](#) (Aug 17)

FDA approved Zelboraf (vemurafenib), a drug to treat patients with late-stage or unresectable melanoma, the most dangerous type of skin cancer.

[FDA approves the first specific treatment for scorpion stings](#) (Aug 3)

FDA approved Anascorp, the first specific treatment for a scorpion sting by Centruroides scorpions in the United States.

For information on drug approvals, please visit [Drugs@FDA](#).

ANNOUNCEMENTS:

[FDA's "Mini-Sentinel" safety pilot program is up and running, demonstrating rapid analysis of medical product safety questions](#) (Aug 29)

FDA's "Mini-Sentinel" pilot program, the Agency's first step towards building a nationwide rapid-response electronic safety surveillance system for drugs and other medical products, is now up and running, enabling scientists to evaluate safety questions far more rapidly than using traditional channels.

[FDA: Regulatory science plan positions agency to foster innovation through better science](#) (Aug 17)

FDA released its "Strategic Plan for Regulatory Science," calling for a sweeping modernization of the science used in developing and evaluating products critical to the nation's health, economy, and security.

[Safe Use Initiative: Acetaminophen Toxicity](#) (Aug 3)

Under the leadership of the National Council for Prescription Drug Programs, FDA's Safe Use Initiative and a broad group of stakeholders came together to form the Acetaminophen Best Practices Task Group, which produced the white paper, "[NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen \(PDF- 974KB\)](#)¹."

[Availability of Spanish language versions of Drug Safety Communications](#)

CDER's Office of Communications has launched a new pilot program to provide Spanish language versions of the agency's Drug Safety Communications (DSCs). Given various time and review constraints, the Spanish version DSCs will generally follow the English version by about 1-2 weeks.

[FDA reopens comment period on proposed 'gluten-free' food labeling rule](#) (Aug 2)

FDA reopened the comment period for its 2007 proposal on labeling foods as "gluten-free." The agency is also making available a safety assessment of exposure to gluten for people with celiac disease and invites comment on these additional data.

On August 2, FDA hosted a stakeholder teleconference concerning the reopening of the comment period on proposed 'gluten-free' food labeling rule. A replay is available until September 2, 2011 by dialing 866-415-8391.

RESOURCES:

[MedWatch Safety Information Resources for Busy Physicians](#)

A video discussing Medwatch Safety Alerts

[FDA Counterfeit Medicine Page Updated](#)

Counterfeit medicine is fake medicine. It may be contaminated or contain the wrong or no active ingredient. Counterfeit drugs are illegal and may be harmful to your health.

[For Health Professionals](#) - Additional information for Health Professionals may be found on FDA's Health Professional website.

[MedWatch Safety Alerts for Human Medical Products](#)

Your FDA gateway for finding clinically important safety information and reporting serious problems with human medical products.

[FDA Drug Info Rounds](#)

A series of training videos for practicing clinical and community pharmacists.

[FDA Basics](#)

Each month, different Centers and Offices at FDA will host an online session where the public can ask questions to senior FDA officials about a specific topic or just listen in to learn more about FDA.

Submitted by CDR Janelle Derbis, PharmD, Office of the Commissioner, Office of Special Health Issues