

## News & Events

### FDA NEWS RELEASE

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### **FDA Issues Early Communication about Ongoing Safety Review of Weight Loss Drug Orlistat** ***Review includes both prescription drug Xenical and OTC drug Alli***

The U.S. Food and Drug Administration announced today that it is reviewing adverse event reports of liver injury in patients taking the weight loss drug orlistat, marketed as the prescription drug Xenical and the over-the-counter medication Alli.

Between 1999 and 2008, the FDA received 32 reports of serious liver injury in patients taking orlistat. Of those cases, 27 reported hospitalization and six resulted in liver failure. Thirty of the adverse events occurred outside the United States. The most commonly reported adverse events included yellowing of the skin or whites of the eyes (jaundice), weakness, and stomach pain.

The FDA is reviewing additional data submitted by orlistat manufacturers on suspected cases of liver injury, and the issue has been discussed at the FDA's Center for Drug Evaluation and Research Drug Safety Oversight Board.

"The issues here are complex, but FDA has benefited from the input of the Board, including comments from representatives from three FDA Centers and several other Agencies in the Department of Health and Human Services," said Steven Osborne, M.D., executive director of the Board.

The FDA's analysis of these data is ongoing, and no definite association between liver injury and orlistat has been established at this time. Consumers taking Xenical should continue to take it as prescribed, and those using over-the-counter Alli should continue to use the product as directed.

Full text of the Early Communication about an Ongoing Safety Review can be found [here](#). The Early Communication is a risk communication tool used by the FDA to inform the public about its ongoing safety reviews of drugs. The FDA will release its findings on orlistat as soon as the review is completed.

Consumers who have used orlistat should consult a health care professional if they experience symptoms possibly associated with development of liver injury, particularly weakness or fatigue, fever, jaundice, or brown urine. Other symptoms may include abdominal pain, nausea, vomiting, light-colored stools, itching, or loss of appetite.

The FDA urges both health care professionals and consumers to report suspected side effects from the use of orlistat to FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, fax, or phone.

-- [Online](#)

--Regular Mail: use postage-paid [FDA form 3500](#) and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

--Fax: 800-FDA-0178

--Phone: 800-FDA-1088

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