FDA Investigates Reports of Liver Damage From Weight Loss Drugs

ROCKVILLE, Md -- August 24, 2009 -- The US Food and Drug Administration (FDA) 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 (OTC) medication Alli.

Between 1999 and 2008, the FDA received 32 reports of serious liver injury in patients taking orlistat. Of those cases, 27 reported hospitalisation and 6 resulted in liver failure. Thirty of the adverse events occurred outside the United States. The most commonly reported adverse events included 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, Rockville, Maryland.

"The issues here are complex, but FDA has benefited from the input of the Board, including comments from representatives from 3 FDA Centers and several other agencies in the Department of Health and Human Services," said Steven Osborne, MD, 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. FDA is not advising healthcare professionals to change their prescribing practices with orlistat; and patients taking prescription orlistat (Xenical) should continue to take it as prescribed, and those using over-the-counter formulation Alli should continue to use the product as directed.

Xenical (orlistat 120mg) was approved as a prescription product by FDA in 1999 for obesity management in conjunction with a reduced caloric diet, and to reduce the risk of regaining weight after prior weight loss. In 2007, Alli (orlistat 60mg) was approved for OTC use for weight loss in overweight adults aged 18 years and older, in conjunction with a reduced-calorie and low-fat diet. Currently, orlistat is approved for marketing in approximately 100 countries. In January 2009, a non-prescription version of orlistat was approved for sale in the European Union.

The FDA will release its findings on orlistat as soon as the review is completed.

Patients 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.

SOURCE: US Food and Drug Administration

From Mike:
The secret of weight control is what you stick in your mouth. Calories from fat being 10% or less is a primary. www.breathing.com/weight-loss-program.htm