# FDA to dieters: Don't use supplement Hydroxycut

US Food and Drug Adminstration – The logo of the US Food and Drug Adminstration (FDA). Dieters who use the weight loss and energy-boosting …

By RICARDO ALONSO-ZALDIVAR, Associated Press Writer Ricardo Alonso-zaldivar, Associated Press Writer – Sat May 2, 10:05 am ET

WASHINGTON – Government health officials warned dieters and body builders Friday to immediately stop using Hydroxycut, a widely sold supplement linked to cases of serious liver damage and at least one death.

The Food and Drug Administration said the company that makes the dietary supplement has agreed to recall 14 Hydroxycut products. Available in grocery stores and pharmacies, Hydroxycut is advertised as made from natural ingredients. At least 9 million packages were sold last year, the FDA said.

Dr. Linda Katz of the FDA's food and nutrition division said the agency has received 23 reports of liver problems, including the death of a 19-year-old boy living in the Southwest. The teenager died in 2007, and the death was reported to the FDA this March.

Other patients experienced symptoms ranging from jaundice, or yellowing of the skin, to liver failure. One received a transplant and another was placed on a list to await a new liver. The patients were otherwise healthy and their symptoms began after they started using Hydroxycut, regulators said.

Iovate Health Sciences, which makes the diet pills, said in a statement that the 2007 death of the teenager was not caused by Hydroxycut. The statement gave no details.

"The number of adverse event reports described by the FDA in its advisory is small relative to the many millions of people who have used Hydroxycut products over the past seven years," said the

company statement. "Iovate's own assessment of the potential risk associated with the use of these products differs from that expressed by the FDA."

On its Web site, the company said it agreed to the recall out of "an abundance of caution." Iovate is based in Canada, with U.S. offices near Buffalo, N.Y. Consumers can get a refund by returning the pills to the store that sold them, the company said.

Dietary supplements aren't as tightly regulated by the government as medications. Manufacturers don't need to prove to the FDA that their products are safe and effective before they can sell them to consumers.

But regulators monitor aftermarket reports for signs of trouble, and in recent years companies have been put under stricter requirements to alert the FDA when they learn of problems. In 2004, the government banned ephedra, an ingredient in many supplements, linked to heart attacks and strokes.

Katz said it has taken so long to get a handle on the Hydroxycut problem because the cases of liver damage were rare and the FDA has no authority to review supplements before they're marketed. "Part of the problem is that the FDA looks at dietary supplements from a post-market perspective, and an isolated incident is often difficult to follow," she said.

The FDA relies on voluntary reports to detect such problems, and many cases are never reported, officials acknowledge.

Health officials said they have been unable to determine which Hydroxycut ingredients are potentially toxic, partially because the formulation has changed several times.

Public health researcher Ano Lobb, who has studied Hydroxycut and other dietary supplements for Consumer Reports, said the problem may be an ingredient called hydroxycitric acid. Derived from a tropical fruit, it's been linked to liver problems in at least one medical journal study. Lobb said it's likely that other supplements containing the same ingredient remain on the market.

"You really have to be careful about dietary supplements, especially weight-loss pills," said Lobb. "People believe that the FDA has verified that these products are at least safe and effective, and that's really not the case. When you see fantastic claims — that's generally what they are."