FDA: Dieters should stop Hydroxycut use now

May 1 2009, By RICARDO ALONSO-ZALDIVAR , Associated Press Writer

(AP) -- 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.

Iovate Health Sciences, which makes the diet pills, said it agreed to the recall out of "an abundance of caution." The company is based in Canada and its U.S. distributor is headquartered near Buffalo, N.Y.

"While this is a small number of reports relative to the many millions of people who have used Hydroxycut products over the years, out of an abundance of caution and because consumer safety is our top priority, we are voluntarily recalling these Hydroxycut-branded products," the company said in a statement on its Web site. Consumers can get a refund by returning the pills to the store they purchased them from, 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."

On the Net:

FDA press release: http://tinyurl.com/cfxjbe