# FDA probes liver damage with weight loss pill alli

August 24 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- The Food and Drug Administration is investigating reports of liver damage in patients taking alli, the only nonprescription weight loss drug approved by the agency.

Regulators said Monday they have received more than 30 reports of liver damage in patients taking alli and Xenical, the prescription version of the drug. The reports, submitted between 1999 and October 2008, included 27 hospitalized patients, and six who suffered liver failure.

Alli and Xenical are both marketed by British drugmaker GlaxoSmithKline, though Xenical is manufactured by Swiss firm Roche.

The FDA says it has not established a direct relationship between the weight loss treatments and liver injury, and advised patients to continue using the drugs as directed.

"Consumers should consult their health care professional if they are experiencing symptoms," the agency said on its Web site. Signs of liver damage include fatigue, fever, nausea and vomiting.

The FDA said it's reviewing additional details about the suspected cases of liver injury submitted by manufacturers.

Roche referred questions to GlaxoSmithKline. Glaxo representatives did not immediately return calls for comment Monday afternoon.

The FDA first approved Xenical in 1999 and alli in 2007. The prescription pill is twice as potent as alli, which can be bought over the counter.

Glaxo reported $123 million in sales for alli last year, while Roche posted $472 million in revenue for Xenical.

In general, the FDA has started notifying the public earlier about possible safety issues with drugs, after coming under fire for acting too slowly on problems with blockbuster treatments like Merck's painkiller Vioxx.

Shares of London-based Glaxo fell 57 cents to $39.46 in afternoon trading.