Impax Gets FDA Warning Label For Manufacturing Practices

HAYWARD, Calif. (AP) — Generic drugmaker Impax Laboratories Inc. said Monday that it received a warning from the Food and Drug Administration about manufacturing practices at its plant in Hayward.

Impax said the warning letter came Friday. It said during a review, FDA inspectors found problems in the company's sampling and testing, its production record review, and the process it used to determine why manufacturing batches did not meet quality specifications.

Based on the inspection results, Impax said it recalled five production lots of the cholesterol drug fenofibrate in March.

The FDA's inspection was conducted between Dec. 13 and Jan. 21.

Impax said it reviewed its manufacturing practices after the inspection and will work to address the FDA's concerns. It is required to respond to the FDA's warning letter within 15 business days. The warning letter does not affect its ability to make and ship products, but the company said marketing applications that involve the Hayward plant could be delayed.

Impax added that it reduced production at the Hayward plant so it could make changes, and it has now resumed production at a normal pace.

Shares of Impax lost $1.14, or 4.5 percent, to $24.51 in midday trading.

Source URL (retrieved on *02/27/2015 - 7:13am*):
http://www.impomag.com/news/2011/06/impax-gets-fda-warning-label-manufacturing-practices