US FDA says Wyeth made false claims about Effexor
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By Susan Heavey

WASHINGTON, March 26 (Reuters) - The U.S. Food and Drug Administration (News - Websites) on Friday warned U.S. drugmaker Wyeth (NYSE:WYE - News) over circulating misleading claims that its antidepressant Effexor outperforms other popular competitors.
Several print materials, including a journal advertisement, misuse data to say more patients suffered fewer symptoms of depression with Effexor than with selective serotonin reuptake inhibitors, or SSRIs, the FDA said.

Wyeth's claim that Effexor is better "has not been demonstrated by substantial evidence or substantial clinical experience," the FDA said in a letter to the company. The letter was released to the public on Friday.

Some SSRIs include Pfizer's (NYSE:PFE - News) Zoloft, Eli Lilly and Co.'s (NYSE:LLY - News) Prozac and GlaxoSmithKline Plc's (London:GSK.L - News) Paxil.

Effexor falls under a different class of drugs called serotonin and norepinephrine reuptake inhibitors, or SNRIs. Both groups of drugs block serotonin, a powerful neurotransmitter that affects mood.

The FDA letter also cited Effexor radio ads for not stating side effects or specific signs of depression -- including lack of interest, appetite loss and suicidal thoughts.

"The advertisement fails to communicate important characteristics necessary to distinguish between major depressive disorder and variations of normal daily functioning," the FDA said.

The agency gave Wyeth until April 1 to respond to the warning. If the company fails to act, the FDA can eventually impose fines and other enforcement actions.

Wyeth spokesperson Douglas Petkus said the company received the FDA letter and would work with the agency.

Shares of Wyeth were down 25 cents, or 0.68 percent, to $36.78 in late afternoon trade the New York Stock Exchange (News - Websites) .

http://biz.yahoo.com/rc/040326/health_wyeth_1.html
