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Pfizer's Geodon Trial Had 'Significant Violations' (Update2)

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(Updates shares in the fifth paragraph.)

By Catherine Larkin

April 20 (Bloomberg) -- Pfizer Inc. failed to ensure proper monitoring of patients and their side effects in a clinical trial, U.S. regulators said today.

The Food and Drug Administration posted a warning letter on its Web site today outlining "significant violations" discovered during an inspection of a Pfizer clinical trial site from May 4 to June 3. The letter, dated April 9, was redacted to remove the name of the medicine and the study. Pfizer spokeswoman Kristen Neese said the study involved tests of the company's bipolar disorder treatment Geodon for use in children.

While Pfizer was warned by the agency in 2005 over lack of study monitoring that led to widespread overdoses, follow-up inspections in 2006 and 2007 also found dosing errors, the FDA said in the documents. The agency ordered the New York-based drugmaker to respond within 15 days with a plan to ensure that its studies comply with federal regulations.

"Pfizer has communicated with the FDA about our conduct of clinical trials and, over the next two weeks, will provide an outline of new and existing processes for preventing similar issues with Pfizer clinical trials in the future," Neese said in an e-mail today.

Pfizer fell 3 cents to $16.76 at 4:05 p.m. in New York Stock Exchange composite trading. The shares have declined 7.9 percent this year.

Geodon's Heart Impact

Geodon prolongs the heart's electrical cycle. Short-term studies suggest children are sensitive to these changes in the heart and may be more susceptible to potentially deadly arrhythmias, according to an FDA staff review. Outside advisers to the agency backed pediatric use in June, with most members calling for more testing to evaluate the risks.

Bristol-Myers Squibb Co.'s Abilify and Johnson & Johnson's Risperdal, now generic, were cleared for pediatric use in 2007. Doctors treating children sometimes prescribe other antipsychotics that aren't approved for pediatric use.

Children ages 7 to 17 accounted for 11 percent of Geodon use in 2008, according to data posted on the FDA's Web site before the advisory panel meeting. While doctors are free to prescribe the drug for this unapproved use, Pfizer isn't permitted by the FDA to promote the medicine to treat children.

Geodon is approved for adults with schizophrenia and manic episodes of bipolar disorder.

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