FDA Halts Amgen Study after Teen Patient Death

WASHINGTON (AP) — Federal health regulators have halted Amgen's studies of its drug Sensipar after the death of a 14-year-old patient in a company trial.

The Food and Drug Administration said Tuesday it is still gathering information about the death, but has shut down all studies of the drug in children.

Sensipar is approved in adults to treat over-activity of the parathyroid gland, which can lead to brittle bones, kidney stones and abdominal pain. It has been used since 2004 to treat symptoms of chronic kidney disease and parathyroid cancer.

Amgen Inc. had been studying the drug to see whether it works in children.

The Thousand Oaks, Calif.-based company said in a statement that it "is working as rapidly as possible to understand the circumstances of what happened."

The FDA said on its website that it is unclear whether Amgen's drug had a role in the patient's death, but it is reminding doctors to prescribe it carefully.

The drug is known to lower calcium levels, sometimes to a dangerous extent.

The agency says doctors should monitor patients' calcium levels monthly to make sure they don't fall to dangerous levels. Signs of a calcium deficiency include muscle cramping, convulsions and burning or prickling sensations.

The most common side effects of the drug in adults include nausea, vomiting and diarrhea.

Amgen reported annual sales of $800 million for Sensipar in 2011, its most recent full-year financial report.

Company shares fell 7 cents to $89.48 in afternoon trading Tuesday.

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