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FDA cites higher death risk in Sanofi drug study

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(AP) -- Federal health regulators are warning doctors that a heart drug from Sanofi was associated with fatal heart problems in a recently halted company study.

The Food and Drug Administration reported Thursday that Sanofi halted a trial of its drug Multaq after there were twice as many heart attacks, strokes and deaths among patients taking the drug compared with patients taking placebo.

Among more than 3,000 patients studied, there were 32 cardiovascular deaths in the Multaq group compared with 14 in the placebo group.

The study involved patients older than 65 with a permanent heart condition known as atrial fibrillation which causes the heart's chambers to pump out of sync. The FDA approved the drug in 2009 for the short-term form of the condition and a related condition known as atrial flutter. However, doctors routinely prescribe drugs for uses other than those listed on the label.

About 241,000 U.S. patients had received a prescription for the twice-a-day pill as of last month.

The FDA said it is still reviewing the trial data and advises patients taking Multaq to talk with their doctor.

Sanofi, based in Paris, said in a statement it still considers the drug

beneficial to patients.

"It is important that Multaq only be used in patients with non-permanent atrial fibrillation or atrial flutter, as per the current U.S. label," a company spokesman said in an email.

The European Medicines Agency is also reviewing the safety of Multaq.

In midday trading, U.S.-listed shares of Sanofi added 5 cents to $39.75.