# FDA reviewing safety of Sanofi's Lantus insulin

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(AP) -- The Food and Drug Administration said Wednesday it is reviewing data on the safety of Lantus, a synthetic insulin made by Sanofi-Aventis SA.

The move comes after a recent, widely publicized study raised the possibility the once-a-day insulin slightly increases risk of cancer.

In a statement, the FDA said patients should not stop taking their insulin without consulting a doctor because of the risk of serious complications, both immediate and long term. Patients with Type 1 diabetes and many with advanced Type 2 diabetes must inject insulin at least once a day to control their blood sugar.

The agency said it is reviewing many sources of safety data for Lantus, including the new study.

Last Friday, the European Association for the Study of Diabetes said a review of an insurance database of 127,000 patients in four European countries found that out of every 100 patients using Lantus for about 1 1/2 years, one additional person developed cancer.

The association called the results inconclusive and urged further study of Lantus, known generically as insulin glargine.

Three of the four studies suggested an increased risk of various types of cancer, the FDA noted. It said the patients were not followed long

enough to conclusively evaluate the risk.

"Further, inconsistencies in findings within and across individual studies raise concerns as to whether an association between the use of insulin glargine and cancer truly exists," the FDA said.

The agency said it is talking with Paris-based Sanofi-Aventis about whether additional safety and effectiveness studies will need to be done. The agency plans to disclose any findings as the review continues, and asked patients and doctors to report any side effects from use of Lantus to the FDA MedWatch Adverse Event Reporting Program.

Since the study results were disclosed, Sanofi-Aventis officials have been defending the safety of Lantus with a company statement, a conference call with analysts and a video message from the chief medical officer.

Other experts and some patient groups, including the American Diabetes Association, have urged patients to talk to their doctor rather than stopping use of Lantus.

It is the company's third-best-selling drug and a key growth driver, with revenue up 28 percent to nearly $3.5 billion last year.

In New York trading Wednesday, Sanofi shares rose $1.06, or 3.6 percent, to $30.55.