FDA orders Trasylol temporarily withdrawn

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The U.S. Food and Drug Administration has temporarily halted the use of the drug Trasylol, which is used to control bleeding during heart surgery.

The FDA said it asked the drug's manufacturer -- the Bayer Pharmaceuticals Corp. of Germany -- to withdraw Trasylol from the U.S. market pending a review of a study at Canada's Ottawa Health Research Institute that suggested the drug might result in an increased death rates.

FDA officials said until the study is reviewed, it is not possible to determine and identify the population of patients undergoing cardiac surgery for which the benefits of Trasylol might outweigh the risks.

Two weeks ago, the FDA was notified the Canadian institute had halted a Trasylol study because the drug appeared to increase the risk of death compared with two other antifibrinolytic drugs used in the study. However the preliminary data from the terminated study also suggested the drug was effective in reducing serious bleeding events during surgical procedures.