FDA News

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FDA Requests Marketing Suspension of Trasylol

The U.S. Food and Drug Administration (FDA) today announced that, at the agency's request, Bayer Pharmaceuticals Corp. has agreed to a marketing suspension of Trasylol, a drug used to control bleeding during heart surgery, pending detailed review of preliminary results from a Canadian study that suggested an increased risk for death.

FDA requested the suspension in the interest of patient safety based on the serious nature of the outcomes suggested in the preliminary data. FDA has not yet received full study data but expects to act quickly with Bayer, the study's researchers at the Ottawa Health Research Institute, and other regulatory agencies to undertake a thorough analysis of data to better understand the risks and benefits of Trasylol.

There are not many treatment options for patients at risk for excessive bleeding during cardiac surgery. Thus, FDA is working with Bayer to phase Trasylol out of the marketplace in a way that does not cause shortages of other drugs used for this purpose.

Until FDA can review the data from the terminated study it is not possible to determine and identify a population of patients undergoing cardiac surgery for which the benefits of Trasylol outweigh the risks. Understanding that individual doctors may identify specific cases where benefit outweighs risk, FDA is committed to exploring ways for those doctors to have continued, limited access to Trasylol.

Two weeks ago, FDA was notified that researchers with the Ottawa Health Institute stopped a study on Trasylol because the drug appeared to increase the risk for death compared to two other antifibrinolytic drugs used in the study. Antifibrinolytic drugs help slow the breakdown of blood clots and subsequent excessive bleeding. The preliminary data from this terminated study also suggested that fewer patients receiving the drug experienced serious bleeding events.

On Oct. 26, FDA issued an Early Communication about an Ongoing Safety Review of Trasylol in response to the Canadian study's termination. In 2006, FDA revised the labeling for Trasylol to strengthen its safety warning and limit its approved usage to patients at an increased risk for blood loss and blood transfusion during coronary bypass graft surgery.

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