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FDA News

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FDA Revises Labeling for Trasylol (Aprotinin Injection) to Strengthen Safety Warnings and Limit Usage of Drug to Specific Situations

The U.S. Food and Drug Administration (FDA) today approved revised labeling for Trasylol (aprotinin injection) to strengthen its safety warnings and to limit its approved usage to specific situations. Trasylol is given to patients before heart surgery to reduce bleeding and the need for blood transfusions. Trasylol is marketed by Bayer Pharmaceuticals Corporation, Leverkusen, Germany.

"The purpose of the label change is to inform physicians and patients about the risks associated with Trasylol and to ensure they understand the new warnings and use the product as directed by the label," said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research.

The new labeling specifies that Trasylol should only be given to patients who are at an increased risk for blood loss and blood transfusion in the setting of coronary bypass graft surgery (a procedure used to improve blood flow to the heart) when patients undergo cardiopulmonary bypass (a procedure that allows a machine to take over the heart's functions when it is stopped during surgery). The changes also include a warning that Trasylol increases the possible risk for kidney damage, and suggest ways to manage and reduce the patient's risk for hypersensitivity (exaggerated immune) reactions.

The labeling changes follow an FDA-conducted review of safety information that FDA became aware of after the product was introduced to the market. FDA began this safety review of Trasylol in January 2006. The review was triggered by the results of two published research studies. One study reported an increase in the possibility of kidney failure, heart attack and stroke in patients treated with Trasylol compared to those treated with other drugs. The other study reported an increase in the possibility of kidney damage compared to other drugs, but did not show an increased risk of heart attack or stroke. On February 8, 2006, FDA issued a Public Health Advisory regarding these new findings with Trasylol. On September 21, 2006, FDA held a public meeting of the Cardiovascular and Renal Drugs Advisory Committee to discuss the safety and overall risk-benefit profile for Trasylol. At that meeting, the committee discussed the findings from the two published observational studies, a Bayer worldwide safety review, and the FDA review of its own post-marketing database, and made recommendations for labeling changes. The labeling changes for Trasylol are based upon the recommendations of that advisory committee.

FDA announced on September 29, 2006, that Bayer informed the agency of an additional safety study on September 27, 2006. The preliminary results from that study suggest that in addition to serious kidney damage, Trasylol may increase the chance for death, congestive heart failure (a weakening of the heart), and strokes. The FDA review of this additional Trasylol safety information is continuing and it may result in other actions,

including additional changes to the labeling. For additional information about Trasylol, see www.fda.gov/cder/drug/infopage/aprotinin/default.htm.

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