Avandia is a drug that is widely used to control diabetes, but there are recent reports that it may increase the risk of heart attacks and death. Avandia is widely used by diabetics to keep their blood sugars at safe levels, but the new reports suggest that it might have side effects that increase the risk for heart attacks and death from such an attack.

Contact us for a free evaluation if you have suffered a heart attack while taking Avandia.

FDA Issues Safety Alert on Avandia

The U.S. Food and Drug Administration (FDA) is aware of a potential safety issue related to Avandia (rosiglitazone), a drug approved to treat type 2 diabetes. Safety data from controlled clinical trials have shown that there is a potentially significant increase in the risk of heart attack and heart-related deaths in patients taking Avandia. However, other published and unpublished data from long-term clinical trials of Avandia, including an interim analysis of data from the RECORD trial (a large, ongoing, randomized open label trial) and unpublished reanalyses of data from DREAM (a previously conducted placebo-controlled, randomized trial) provide contradictory evidence about the risks in patients treated with Avandia.

Patients who are taking Avandia, especially those who are known to have underlying heart disease or who are at high risk of heart attack should talk to their doctor about this new information as they evaluate the available treatment options for their type 2 diabetes.

FDA's analyses of all available data are ongoing. FDA has not confirmed the clinical significance of the reported increased risk in the context of other studies. Pending questions include whether the other approved treatment from the same class of drugs, pioglitazone, has less, the same or greater risks. Furthermore, there is inherent risk associated with switching patients with diabetes from one treatment to another even in the absence of specific risks associated with particular treatments. For these reasons, FDA is not asking GlaxoSmithKline, the drug's sponsor, to take any specific action at this time. FDA is providing this emerging information to prescribers so that they, and their patients, can make individualized treatment decisions.

"FDA remains committed to assuring that doctors and patients have the latest information available to make treatment and medication use decisions. In this case, FDA is carefully weighing several complex sources of data, some of which show conflicting results, related to the risk of heart attack and heart-related deaths in patients treated with Avandia," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research. "We will complete our analyses and make the results available as soon as possible. FDA will take the issue of cardiovascular risk associated with Avandia and other drugs in this class to an Advisory Committee as soon as one can be convened."

Avandia was approved in 1999 for treatment of type 2 diabetes, a serious and life threatening disease that

affects about 18 to 20 million Americans. Diabetes is a leading cause of coronary heart disease, blindness, kidney failure and limb amputation. Since the drug was approved, FDA has been monitoring several heart-related adverse events (e.g., fluid retention, edema and congestive heart failure) based on signals seen in previous controlled clinical trials of Avandia alone and in combination with other drugs, and from postmarketing reports. FDA has updated the product's labeling on several occasions to reflect these new data, most recently in 2006. The most recent labeling change for Avandia also included a new warning about a potential increase in heart attacks and heart-related chest pain in some individuals using Avandia. This new warning was based on the result of a controlled clinical trial in patients with existing congestive heart failure.

Recently, the manufacturer of Avandia provided FDA with a pooled analysis (meta analysis) of 42 randomized, controlled clinical trials in which Avandia was compared to either placebo or other anti-diabetic therapies in patients with type 2 diabetes. The pooled analysis suggested that patients receiving short-term (most studies were 6-months duration) treatment with Avandia may have a 30-40 percent greater risk of heart attack and other heart-related adverse events than patients treated with placebo or other anti-diabetic therapy. These data, if confirmed, would be of significant concern since patients with diabetes are already at an increased risk of heart disease.

Avandia is manufactured by GlaxoSmithKline, which is based in Research Triangle Park, N.C.

Consumer Inquiries: 888-INFO-FDA