

# Manufacturers of Some Diabetes Drugs to Strengthen Warning on Heart Failure Risk

August 15, 2007 -- The U.S. Food and Drug Administration today announced manufacturers of certain drugs approved to treat Type 2 diabetes have agreed to add a stronger warning on the risk of heart failure, a condition that occurs when the heart does not adequately pump blood. The information will be included in the form of a "boxed" warning—FDA's strongest form of a warning. The upgraded warning emphasizes that the drugs may cause or worsen heart failure in certain patients.

After a review of postmarketing adverse event reports, FDA determined that an updated label with a boxed warning on the risks of heart failure was needed for the entire thiazolidinedione class of antidiabetic drugs. This class includes Avandia (rosiglitazone), Actos (pioglitazone) Avandaryl (rosiglitazone and glimepiride), Avandamet (rosiglitazone and metformin), and Duetact (pioglitazone and glimepiride). These drugs are used in conjunction with diet and exercise, to improve blood sugar control in adults with type 2 (non-insulin-dependent) diabetes. FDA had asked the drug's manufacturers, GlaxoSmithKline and Takeda, to address these concerns.

"Under FDA's postmarketing surveillance program, we carefully monitor new safety information for marketed drugs and take appropriate action when necessary to inform patients and health care providers of new information," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research. "This new boxed warning addresses FDA's concerns that despite the warnings and information already listed in the drug labels, these drugs are still being prescribed to patients without careful monitoring for signs of heart failure."

FDA's review of adverse event reports found cases of significant weight gain and edema—warning signs of heart failure. In some reports, FDA noted, continuation of therapy has been associated with poor outcomes, including death.

The strengthened warning advises health care professionals to observe patients carefully for the signs and symptoms of heart failure, including excessive, rapid weight gain, shortness of breath, and edema after starting drug therapy. Patients with these symptoms who then develop heart failure should receive appropriate management of

the heart failure and use of the drug should be reconsidered. People who have questions should contact their health care providers to discuss alternative treatments.

The warning also states that these drugs should not be used by people with serious or severe heart failure who have marked limits on their activity and who are comfortable only at rest or who are confined to bed or a chair.

FDA's review of Avandia and possible increased risk of heart attacks is ongoing. On July 30, 2007, FDA's Endocrine and Metabolic Advisory Committee and the Drug Safety and Risk Management Advisory Committee recommended that Avandia continue to be marketed, and further recommended that information be added to the labeling for risk of heart attacks (ischemic risks).

For more information, visit:

[Rosiglitazone maleate \(marketed as Avandia, Avandamet, and Avandaryl\) Information](#)  
[Pioglitazone HCl \(marketed as Actos and Duetact\) Information](#)

Source: Food and Drug Administration