



# Consumer Alert

August 28, 2007

## **URGENT! EMERGING THERAPEUTIC ISSUES COMMUNICATION**

On August 14, 2007, the U.S. Food and Drug Administration (FDA) informed healthcare professionals that a **BOXED WARNING**, highlighting the risk of congestive heart failure, is now included in the prescribing information for products containing Actos® (pioglitazone – Takeda) and Avandia® (rosiglitazone – GlaxoSmithKline). Heart failure is a condition in which the heart can't pump enough blood to the body's other organs. Actos and Avandia belong to the class of diabetes medications known as thiazolidinedione, or 'glitazones'. Here is some important information included in the recent labeling change:

- **Glitazones can cause or exacerbate congestive heart failure.**
- **Patients should be monitored for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema) after initiating therapy or dose increases.**
- **Glitazones therapy is not recommended in patients with symptoms of heart failure and is *contraindicated* in patients with established heart failure (NYHA Class III or IV).**

For additional information about these changes or to report an adverse event, please access FDA's MedWatch website at: [www.fda.gov/medwatch/safety.htm](http://www.fda.gov/medwatch/safety.htm). You can also call FDA at 1-888-INFO-FDA (automated) or 301-827-4570.

On July 30, 2007, an FDA advisory panel discussed the safety of Avandia and a possible link to heart attacks. The above labeling changes are not a direct result of this meeting. FDA has yet to formally react to the committees' recommendations. As a result, additional changes to Avandia's product labeling may occur.

***This communication is not intended to be legal advice and should not be construed as legal advice. If you have any legal questions or concerns about your plan, GBS recommends seeking counsel from an ERISA attorney.***

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