

FDA Reprimands Glaxo for Avandia Study

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The US Food and Drug Administration Federal (FDA) has just issued a warning to the drug maker, GlaxoSmithKline, for not reporting safety results on its diabetes pill Avandia. Avandia received the prominent, "Black Box" warning label last year and the FDA said that between 2001 and 2007 GlaxoSmithKline neglected to update the agency on over 10 ongoing studies of Avandia, as required by regulations. The FDA acknowledges that information from those studies were included and disclosed in other notices to the government; however, the FDA categorizes the omissions as "serious," saying that the omissions "may be symptomatic of underlying post-market reporting failures."

Last November, Avandia received a Black Box warning, which is the most serious labeling warning that a drug can carry. A Black Box warning was posted on the medication as a means to alert doctors and patients that Avandia could increase the risk of heart attacks. The labeling change to the Black Box followed several high-profile congressional hearings where FDA and Glaxo were criticized for not disclosing the drug's potential risks earlier. Today, a spokeswoman for Glaxo said the FDA had all safety studies on Avandia before it added the Black Box warning last year, adding that Glaxo is working with the FDA to resolve the issues.

Glaxo has agreed to the FDA's demand for a major study that will directly review Avandia's heart effects. The study is not expected to be complete until 2014.

Meanwhile, lawsuits against GlaxoSmithKline over Avandia are emerging and many more lawsuits are expected to be filed. One man is suing GlaxoSmithKline in federal court, claiming Avandia caused him to have to undergo heart bypass surgery. Attorneys allege that the drug maker should have known that Avandia—which is prescribed to improve blood sugar in type 2 diabetes patients—is linked to a significant and increased risk of heart failure, heart attack, and stroke.

The FDA refuses to withdraw Avandia from the market, but has asked Glaxo to conduct the long-term study that will compare Avandia with other type 2 diabetes drugs. The trial will likely commence in a year; however, it will be years before the study is complete and the results are made available. Patient advocates and FDA critics consider the recent Black Box warning for Avandia to be a feeble response to Avandia's ongoing safety issues, requesting that Avandia be pulled from the market. Meanwhile, the American Diabetes Association and the European Association for the Study of Diabetes recently released a revised consensus statement that stated that the emerging information suggests that there are additional hazards associated with Avandia and that the drug may result in increased risk of myocardial infarctions. The US Department of Veterans Affairs also recently announced that it was dropping Avandia from its drug formulary because, in some, Avandia did not afford the same margin of safety as some other diabetes drugs. A Congressional Committee Report also found that Glaxo executives had intimidated a diabetes expert into keeping quiet about Avandia's safety problems.