

FDA NEWS RELEASE

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FDA significantly restricts access to the diabetes drug Avandia
Makes regulatory decisions on RECORD and TIDE trials

The U.S. Food and Drug Administration today announced that it will significantly restrict the use of the diabetes drug Avandia (rosiglitazone) to patients with Type 2 diabetes who cannot control their diabetes on other medications. These new restrictions are in response to data that suggest an elevated risk of cardiovascular events, such as heart attack and stroke, in patients treated with Avandia.

“The FDA is taking this action today to protect patients, after a careful effort to weigh benefits and risks,” said FDA Commissioner Margaret A. Hamburg, M.D. “We are seeking to strike the right balance to support clinical care.”

Rosiglitazone also is available in combination with other diabetes medications, metformin under the brand name Avandamet or glimepiride under the brand name Avandaryl.

Avandia, manufactured by GlaxoSmithKline (GSK), is in a class of drugs known as thiazolidinediones, or TZDs. It is intended to be used in conjunction with diet and exercise to improve glucose (blood sugar) control in patients with Type 2 diabetes mellitus.

The FDA will require that GSK develop a restricted access program for Avandia under a risk evaluation and mitigation strategy, or REMS. Under the REMS, Avandia will be available to new patients only if they are unable to achieve glucose control on other medications and are unable to take Actos (pioglitazone), the only other drug in this class. Current users of Avandia who are benefiting from the drug will be able to continue using the medication if they choose to do so.

Doctors will have to attest to and document their patients' eligibility; patients will have to review statements describing the cardiovascular safety concerns associated with this drug and acknowledge they understand the risks. The agency anticipates that the REMS will limit use of Avandia significantly.

“Allowing Avandia to remain on the market, but under restrictions, is an appropriate response, given the significant safety concerns and the scientific uncertainty still remaining about this drug,” said Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research.

Also today, the FDA ordered GSK to convene an independent group of scientists to review key aspects of the company’s clinical trial known as RECORD, which studied the cardiovascular safety of Avandia compared to standard diabetes drugs. During the course of the FDA’s review of the RECORD study, important questions arose about potential bias in the identification of cardiovascular events. The FDA is requiring this independent review to provide additional clarity about the findings.

In addition, the agency halted the GSK's clinical trial known as TIDE and rescinded all of the regulatory deadlines for completion of the trial. The TIDE trial compares Avandia to Actos and to standard diabetes drugs.

The FDA may take additional actions after the independent re-analysis of RECORD is completed.

For more information:

Avandia Update

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm226956.htm>

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