

FDA Narrowly Backed Avandia®

By JENNIFER CORBETT DOOREN *October 30, 2007*

WASHINGTON -- An internal Food and Drug Administration drug-safety oversight board narrowly voted to keep GlaxoSmithKline PLC's diabetes drug Avandia® on the market, according to Senate Finance Committee investigators.

Sen. Charles Grassley (R., Iowa), the top Republican on the panel, who has been investigating the FDA's handling of drug-safety issues, said the drug-safety oversight board voted 8-7 earlier this month to keep Avandia® on the U.S. market.

FDA officials have acknowledged there has been a split within the agency about whether to pull Avandia® off the market or allow it to stay on the market with a tougher "black box" warning that the drug raises the risk of heart attacks. An outside panel of medical experts voted 22-1 on July 30 to keep Avandia® on the market, but several panel members said the drug should have stricter warnings. The FDA usually follows its panel's advice but isn't required to do so. A black-box warning is the FDA's strongest drug warning.

The FDA and GlaxoSmithKline have said they are working to finalize a new drug label for Avandia® but won't discuss the specifics.

Sen. Grassley criticized the FDA for not making details of the drug-safety oversight board's meeting on Avandia® public. "The Avandia® case continues to present new rounds of questions about the way the FDA monitors and assesses drug risks and decides whether to let the public know about emerging risks," he said.

An FDA spokeswoman declined to comment on the matter but said the agency would respond to Sen. Grassley.