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Breaking News

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FDA Mulls Removing Diet Drug From U.S. Market



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Of DOW JONES NEWSWIRES

WASHINGTON -(Dow Jones)- A federal advisory panel is being asked to help decide whether Abbott Laboratories' (ABT) weight-loss drug Meridia should stay on the market.

Meridia has been the subject of an on-going safety review. Earlier this year the European Medicines Agency ordered Abbott to remove Meridia from the European market and the FDA toughened warnings on the drugs' label saying it shouldn't be used in patients with a history of heart problems. At the time, the FDA also said the product should be discontinued in patients who do not lose at least 5% of their baseline body weight within the first three to six months of treatment.

Now the FDA is considering whether to remove the product from the U.S. market. Meridia will be discussed Wednesday by the agency's endocrinologic and metabolic drugs advisory committee, which is made up of non-FDA medical experts.

The panel is being asked to vote on what additional regulatory action it thinks the FDA should take, including whether the product should be withdrawn from the U.S. market. The FDA usually follows the advice of its advisory committee but isn't required to do so. The FDA posted background materials for Wednesday's meeting on its website Monday.

The panel will primarily discuss a clinical study known as Scout, which was conducted in patients with a history of heart disease or diabetes. It showed patients in the study had a higher rate of cardiovascular events compared to patients on a placebo medication.

An FDA clinical review of the study said, "in a population of middle-age and older overweight and obese subjects, treatment with [Meridia] for an average of 3.5 years increased the relative risk for major adverse cardiac events by 16%." However, the FDA said the data from the study haven't been fully analyzed.

According to another FDA memo, agency staff said there was evidence while that Meridia improved some cardiac risk factors but that it "may have a detrimental effect on others," such as an increase in blood pressure and heart rate. Still, the memo said, given the modest decrease in body weight seen with most patients taking Meridia, "even a small increase in cardiovascular risk seems unwarranted."

In a document also posted to the FDA's web site, Abbott said use of Meridia in the target population currently described on the product's label is associated with a low rate of cardiovascular events.

The company said it supports placing a boxed warning on the product giving doctors "advice on monitoring and discontinuation of therapy based on blood pressure, pulse, and weight loss parameters." A boxed warning is FDA's toughest warning on a drug label.

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