FDA scrutinizes weight loss pill from Orexigen

December 3 2010, MATTHEW PERRONE , AP Health Writer

(AP) -- Scientists for the Food and Drug Administration said Friday a pill to treat obesity from Orexigen Therapeutics Inc. helped patients lose weight, though it didn't meet all the criteria set forth by the agency.

The FDA's review, posted online Friday, also raised questions about the pill's effects on the heart, a perennial issue for weight loss drugs that have been plagued by safety issues.

Orexigen's pill Contrave is the third weight loss pill to be reviewed by the FDA this year. FDA officials have acknowledged the need for new weight loss drugs amid an epidemic of U.S. obesity, though the agency rejected the two other medications due to safety concerns.

Shares of Orexigen Therapeutics Inc., based in La Jolla, Calif., fell 73 cents, or 13 percent, to $4.74 in morning trading.

The FDA said Friday four studies conducted by Orexigen showed patients taking its drug lost, on average, 4.2 percent more weight than patients taking a placebo. However, the results did not meet an FDA guideline that there should be at least a 5 percent difference in weight loss between the groups.

The drug did meet a second measure of effectiveness involving the number of patients who lost at least 5 percent or more of their weight. FDA guidelines published in 2007 state that a drug can be considered effective if it meets this requirement.

The FDA will ask a panel of experts to vote on the drug's efficacy and safety on Tuesday. The vote is non-binding, though the FDA often follows the guidance of its panelists.

With U.S. obesity rates nearing 35 percent among adults, doctors and public health officials say new weight-loss therapies are desperately needed. And even a modestly effective drug could have blockbuster potential.

But the search for a drug that helps patients safely shed pounds has been largely unsuccessful. Earlier this year Abbott Laboratories' Meridia weight loss pill was pulled from the market after regulators said it increased the risk of heart attack and stroke.

In reviewing Contrave, FDA scientists complained that the company enrolled few elderly patients or patients with a history of heart disease in its trials, making it difficult to determine the drug's safety in patients at risk for heart attack and stroke.

Contrave is a combination pill, mixing the antidepressant bupropion with the anti-addiction drug naltrexone. FDA reported higher rates of side effects already linked to the drugs, including high blood pressure, dizziness and insomnia.

The quest for a blockbuster weight loss drug has been plagued for decades by safety issues. Doctors and patients had hoped a new wave of treatments submitted to the FDA would prove safer than older therapies. But in October the FDA rejected two drugs in one week: Qnexa from Vivus Inc. and lorcaserin from Arena Pharmaceuticals Inc.

Qnexa had shown significant weight loss in trials but was linked to potential heart problems and birth defects. In lorcaserin's case, the FDA raised concerns about cancerous tumors seen in rats who took the drug.