FDA Approves Obesity Pill Belviq For Weight-Related Health Problems

(CBS News) The obesity pill Belviq (lorcaserin) has been approved by the U.S. Food and Drug Administration to be used in conjunction with diet and exercise as a weight management treatment option. It's the first new long-term weight loss drug to hit the U.S. market in over a decade.

The FDA announced Wednesday that the drug is approved for adults with a body mass index (BMI) of 30 or over - which indicates obesity - or with a BMI of 27 or greater (overweight) who have at least one weight-related health problem such as high blood pressure, Type 2 diabetes or high cholesterol. It is manufactured by Switzerland-based Arena Pharmaceuticals.

"Obesity threatens the overall well being of patients and is a major public health concern," Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, said in a written statement. "The approval of this drug, used responsibly in combination with a healthy diet and lifestyle, provides a treatment option for Americans who are obese or are overweight and have at least one weight-related comorbid condition."

There are currently two prescription drugs used to treat obesity including the appetite-suppressant phentermine, and orlistat (Xenical), which prevents dietary fat from being absorbed by the intestine. Orlistat is sold over-the-counter as Alli in a lower dose.

The FDA cited three studies of nearly 8,000 overweight and obese patients - with or without Type 2 diabetes - who were treated from 52 weeks to 104 weeks with the drug or a placebo, along with exercise and diet counseling. The studies found about 47 percent of patients without Type 2 diabetes lost at least 5 percent of their body weight compared with about 23 percent of patients treated with placebo. In people with Type 2 diabetes, about 38 percent of patients treated with Belviq lost at least 5 percent of their body weight, compared to 16 percent in patients treated with placebo.

In May, a panel of expert advisers to the FDA voted 18-4 with one abstention to recommend the agency approve the pill saying its benefits "outweigh the potential risks when used long term."

Earlier this year a rival drug, Vivus Inc.'s Qnexa, won endorsement from an FDA panel after previously being rejected due to safety concerns. The drug's approval is currently pending.