FDA considers appetite-curbing implant for severely obese

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Agency committee weighs application of nerve-stimulating device.

(HealthDay)—A new implant designed to curb the appetite by electrically stimulating stomach nerves is under review Tuesday by a key advisory committee of the U.S. Food and Drug Administration.

The device is aimed at severely obese adults who have failed to slim down using traditional methods, but don't want, or can't have, weight-loss surgery, the manufacturer, EnteroMedics Inc., said in its application for FDA approval.

In the United States, more than one-third of adults are obese, according to the U.S. Centers for Disease Control and Prevention. This increases their risk of serious health issues such as heart disease, diabetes, depression and cancer, experts say.

Despite this, "we have very few tools at our disposal compared with other chronic diseases," said Martin Binks, an associate professor at Texas Tech University who will testify before the FDA panel on behalf of the Obesity Society.

"We certainly are encouraged by the FDA's recent willingness to review treatments for obesity, and we're hopeful the FDA will give a fair hearing and evaluate the device based on the merits," Binks said.

The Maestro Rechargeable System, as it's called, sends electrical signals to nerves around the stomach that help control digestion. These signals block the nerves, decreasing hunger pangs and making the person feel full, the St. Paul, Minn., manufacturer said.

In clinical trials, obese people with a Maestro implant lost an average 8.5 percent more weight than others who received a fake implant, the device maker said.

"The Maestro Rechargeable System is a safe and effective treatment option for obese individuals who have failed more conservative weight reduction interventions such as diet/exercise and pharmacotherapy, but are not able or willing to undergo more aggressive bariatric surgical options," the device company said in FDA briefing papers.

The implant's safety and effectiveness will be evaluated by the gastroenterology and urology devices panel of the FDA's Medical Devices Advisory Committee.

The Maestro consists of a "pulse generator" surgically implanted under the skin of the chest wall. This delivers high-frequency electrical pulses to leads laid along two trunks of the vagus nerve, which helps control the function of many organs in the abdomen.

The device is intended in use for people with a body mass index (BMI) of at least 40, which is extremely obese. BMI is a measurement of body fat based on height and weight.

EnteroMedics said the Maestro also could be used in people with a BMI of at least 35 who have health problems related to their obesity and have failed to lose weight through other programs. (A BMI of 30 is

the threshold for obesity.)

The FDA advisory committee's review will include results from a clinical trial that involved more than 200 morbidly (severely) obese people in the United States and Australia. Of those, 157 received a Maestro implant and 76 received a fake implant.

All of the participants then went through a standard weight management program, which consisted primarily of 15-minute counseling sessions. The program did not include more intense interventions such as very low calorie diets, mandatory exercise programs or portion-controlled meals.

Over the course of a year, study participants with the Maestro implant lost just over 24 percent of their excess weight on average, compared with nearly 16 percent of excess weight loss for people who received fake implants.

More than half the participants lost at least one-fifth of their excess weight, and 38 percent lost at least one-quarter of their excess weight, according to the researchers.

EnteroMedics added that people with fake implants regained about 40 percent of the weight they had lost within six months of the trial's end, while the people with the Maestro device appeared to sustain their weight loss.

The device appears to be largely safe, with only about 4 percent of patients suffering a health problem because of the implant, the FDA's report on Maestro says.

However, the Maestro is unsafe during MRI scans and will have to be removed if a person needs an MRI, according to the FDA. The advisory panel has been asked to consider this as a potential risk in its evaluation.

More information: For more on obesity, visit the U.S. National Library of Medicine.

obese.html