FDA requests market withdrawal of diet drug Belviq due to cancer risk

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A clinical trial of the weight-loss drug Belviq (lorcaserin) shows an

association with an increased risk of cancer, and the U.S. Food and Drug Administration is requesting that its maker withdraw the drug from the U.S. market.

Eisai Inc. has already "submitted a request to voluntarily withdraw the drug," Dr. Janet Woodcock, who directs the FDA's Center for Drug Evaluation and Research, noted in a statement issued Thursday.

Now, "we're taking steps to notify the public," she said, adding that "our review of the full clinical trial results shows that the potential risk of cancer associated with the drug outweighs the benefit of treatment."

Woodcock said the FDA is advising that "patients should stop using the medication Belviq and Belviq XR [lorcaserin] and talk to their health care professionals about other treatment options for weight loss. Health care professionals should stop prescribing and dispensing Belviq and Belviq XR."

The agency first announced that Belviq might have links to cancer in a communication issued Jan 15.

At the time, the FDA said "we cannot conclude that lorcaserin contributes to the cancer risk," but "wanted to make the public aware of this potential risk. We are continuing to evaluate the clinical trial results and will communicate our final conclusions and recommendations when we have completed our review."

That review appears to have led to calls for the voluntary withdrawal of the medication.

Belviq increases feelings of fullness so that people eat less. It's available as a tablet (Belviq) and an extended-release tablet (Belviq XR).

According to the FDA, Belviq was first approved in 2012 as an add-on therapy to help aid weight loss, along with diet and exercise, in people who were obese or overweight.

Contingent on approval, the FDA ordered a randomized, placebo-controlled trial be conducted involving 12,000 people tracked for more than five years.

The trial wrapped up in June 2018, and the data showed that while 7.1% of those taking a "dummy" placebo developed cancer, that number rose to 7.7% among those taking Belviq.

"A range of cancer types was reported," the FDA said. "Several different types of cancers occurred more frequently among patients treated with Belviq, including pancreatic, colorectal and lung cancer. During the trial, one additional cancer per 470 patients treated with the medication for one year was observed."

People who have already taken Belviq should stop taking it, but "the FDA is not recommending special screening for patients who have taken Belviq," Woodcock said.

More information: There's more on maintaining a healthy weight at the American Heart Association.