Watchdog group makes 2nd push to ban diet pill

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(AP) -- For the second time in five years, public health advocates are calling on the Food and Drug Administration to ban a fat-blocking drug sold over-the counter and via prescription, pointing to new reports of kidney stones and pancreatic damage.

Public Citizen filed a petition with the FDA Thursday calling on the agency to remove GlaxoSmithKline's Alli and Roche's Xenical from the market. Alli is sold over-the-counter while Xenical, a higher dose of the drug, is only available with a doctor's prescription. Sales of both versions have been declining for years.

Public Citizen says it identified 47 cases of acute pancreatitis and 73 kidney stones among patients taking the drugs. The reports were culled from the FDA's public database of negative drug reactions.

Known chemically as orlistat, the drug works by blocking the absorption of about one-quarter of any fat consumed. It is the only prescription weight loss drug available for long-term use, though appetite-suppressing drugs like phentermine are available for short-term use.

Orlistat has never been popular, in part due to unpleasant side effects, including oily, loose stools. Marketing materials for Alli stress the importance of keeping meals under 15 grams of fat to avoid oily stools. Educational pamphlets even recommend people start the program when they have a few days off work, or to bring an extra pair of pants to the office.

Annual sales of Alli have declined 42 percent to $84 million in 2010 since its initial launch in 2007. Prescriptions of Xenical have fallen to 110,000 last year from 2.6 million in fiscal year 2000, according to data from the FDA and IMS Health.

Last year the FDA added warnings to Xenical and Alli about rare reports of liver damage.

In light of the drug's side effects and meager health benefit — patients typically lose about 3 percent of their weight after a year — Public Citizen says the drug should be removed from the market.

"Orlistat is a drug used to treat people who are either overweight or obese," states the petition. "Unfortunately, it has little clinical effectiveness and has the potential to damage a number of organs, including the liver, pancreas, and kidneys."

GlaxoSmithKline said in a statement that its drug is "the most studied weight loss medicine. Its safety has been established through 100 clinical studies involving more than 30 thousand patients." The company is based in London with U.S. headquarters in Raleigh, N.C.

A spokesman for Roche could not immediately provide comment Thursday morning.

Public Citizen filed a similar petition to ban the orlistat in 2006, based on scientific studies linking it to precancerous lesions in rats. That petition only applied to the prescription version Xenical, which has been available in the U.S. since 1999.

Any U.S. citizen can file a petition with the FDA to ban a drug or medical device for safety issues. Most petitions are rejected, though Public Citizen has a rare track record of successful drug withdrawals.

Last year, both the diet pill Meridia and painkiller Darvon were both withdrawn from the U.S. market, years after Public Citizen filed petitions against them.

The quest for a blockbuster weight loss drug has been plagued for decades by safety issues. The most notable failure was Wyeth's diet pill-drug combination, fen-phen, which was pulled off the market in 1997 because of links to heart-valve damage and lung problems.