FDA poised to recall unproven blood pressure drug

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(AP) -- Federal health regulators are pushing to withdraw a blood pressure drug that has been on the market for 14 years in spite of the manufacturer's failure to submit evidence that it actually helps patients.

The Food and Drug Administration approved Shire Laboratories' drug ProAmatine in 1996 based on promising early results in treating low blood pressure. But the company has never submitted a mandatory follow-up study to actually prove the long-term benefits of the drug.

In letter to the company posted online Monday, the FDA proposes withdrawing the drug from the market and gives Shire an opportunity to schedule a hearing to discuss the matter. The letter marks the first time the FDA has threatened to pull a drug off the market due to missing follow-up data, though it has long held that power.

"This proposal is necessitated by Shire's failure to conduct postmarketing clinical trials that verify and describe the clinical benefit" of ProAmatine, the agency states.

Calls placed to Shire for comment were not immediately returned.

Copies of the letter were also sent to five generic drugmakers who manufacture the drug, including Mylan Pharmaceuticals and Sandoz Inc. Those generic products would also be subject to a market withdrawal, unless their manufacturers complete the study requested by the FDA.

The letter does not cite any safety or effectiveness problems with the drug, and suggests the action is primarily aimed at enforcing drug approval regulations that have not always been enforced.

ProAmatine is part of a family of heart drugs that help stimulate dangerously low blood pressure. Several companies sell generic versions of the drug phenylephrine, a leading alternative.

For nearly 20 years, the FDA has granted accelerated approval to drugs based on so-called surrogate endpoints, or initial measures that suggest the drug will make real improvements in patient health. In cancer drugs, for example, tumor shrinkage is considered a predictor of increased survival.

Drugmakers favor the program because it helps them get products to market sooner.

But the program has not escaped criticism from government watchdogs.

Last fall the Government Accountability Office issued a report saying the FDA should do more to track whether drugs approved based on preliminary results actually live up to their promise.

The report singled out ProAmatine as a particularly egregious example of missing follow-up data. The government watchdog said that ProAmatine has generated more than $257 million in sales even though "the clinical benefit of the drug has never been established."

According to the GAO, the FDA has never once pulled a drug off the market due to missing or unimpressive follow-up data.

The GAO's September 2009 report found that the FDA had requested 144 follow-up studies for drugs since 1992. Of those about 64 percent

had been completed and more than one-third were still pending.