

FDA relents from midodrine withdrawal plan

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(AP) -- Federal regulators have backed off a plan to remove a Shire PLC low blood-pressure treatment from the market after warning in August that the drug has not been proven effective.

Food and Drug Administration representative Sandy Walsh said in an emailed statement that the agency will continue to allow access to ProAmatine, also known as midodrine, "while the necessary data is collected and the legal issues get sorted out."

Roughly 100,000 U.S. patients received prescriptions for ProAmatine or generic versions last year, according to the FDA. The drug is approved to treat orthostatic hypotension, a type of low [blood pressure](#) that causes patients to become dizzy or faint when standing upright.

Last month, the FDA proposed withdrawing the drug from the market and giving Shire, which is based in Ireland, an opportunity to schedule a hearing to discuss the matter. It had approved ProAmatine in 1996 based on promising early results in treating low blood pressure. But a mandatory follow-up study to actually prove the long-term benefits of the drug was never conducted.

Shire acquired the drug when it bought Roberts Pharmaceuticals in 2000. Shire spokeswoman Jessica Mann said the drugmaker did conduct follow-up trials and submitted data in 2005 that it believes showed its effectiveness. The company plans to continue to work with the FDA.

Shire had said it was planning to withdraw the drug from the market by

Sept. 30. But the company no longer intends to do so.

"It's our goal to do what we can to ensure that this treatment is still available to patients," Mann said.

The FDA's letter marked the first time it threatened to pull a drug off the market due to missing follow-up data, though it has long held that power. FDA spokeswoman Sandy Walsh said in an e-mail the issue "continues to evolve," and that it will know more in the coming weeks.

Copies of the letter also were sent to five generic drugmakers who make the drug, including Mylan Inc. and [Novartis](#) AG unit Sandoz Inc. The generic versions would also be subject to a market withdrawal, unless their manufacturers complete the study requested by the FDA.

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