Shire PLC is withdrawing its low-blood pressure drug ProAmatine [1] from the market following demands from the FDA for additional clinical tests. The drug was approved in 1996 to treat orthostatic hypotension under the FDA’s accelerated approval process that allows companies to bring lifesaving drugs to market quickly and perform post-marketing clinical trials later.

But the FDA viewed Shire’s post-marketing studies as inconclusive and wanted the company to perform more tests which Shire said wasn’t worthwhile since annual revenues for the drug total only $500,000. The FDA proposed Monday withdrawing the drug from the market, and the company responded by pulling its application.

The FDA has been criticized [2] for allegedly letting companies ignore their commitments to perform postmarketing studies, so the withdrawal announcement was seen by some as signaling that the agency is increasing its postmarketing oversight.

Dr. Ross weighed in by telling Clinical Trials Advisor that companies need to follow up on their promises. (The article can be viewed here [3], but a subscription is required)

I think it’s appropriate that drugs approved by the FDA, based on small clinical trials Phase I, II and III be required to have postmarketing studies done to see if there’s a toxicity or adverse reaction in large populations of patients taking the drug that was not detected in the relatively small premarket studies, he told CTA.

(On an unrelated note, we want to point out two additional ACSH press mentions. Esquire’s Mark Warren yesterday told readers [4], For the real story on the FDA and Avastin, please read this piece [5] by Henry I. Miller, who was with the FDA from 1979 to 1994, and Jeff Stier, who is an associate director of the American Council on Science and Health. Stier is also cited in this article [6] today by Reason’s Jacob Sullum on how UCLA epidemiologist and ACSH trustee James Enstrom has been fired for reporting unhelpful results.)