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FDA slams Shionogi for eyeing profit over patient safety

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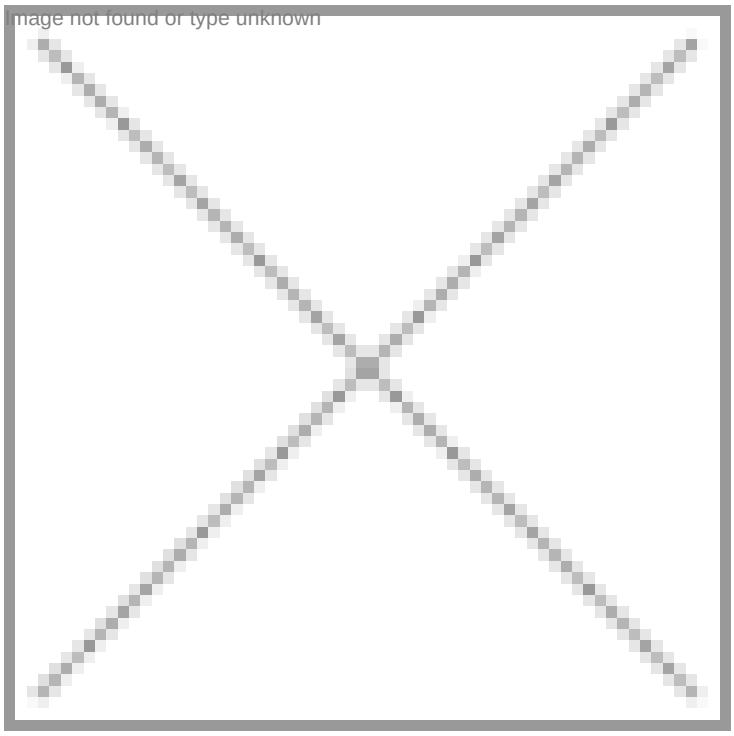

Singapore: The FDA had during September 2012 informed Shionogi that it need to conduct two clinical trials in order to evaluate the risk of irregular heartbeat associated with its Rybix painkiller.

Although Shionogi had informed the FDA that a draft protocol was due in February 2013 and a final report is expected by September 2014, the company during November 2012 wrote to the agency revealing that, "the costs of participating in the post-marketing requirement (PMR) were not commercially justified based on the sales potential for Rybix."

Moreover, instead of withdrawing the product immediately, Shionogi asked the FDA if shipments of existing stock could continue through September 2013, "or when unexpired inventory is depleted, whichever occurs first."

The FDA reminded Shionogi that its obligations for PMR are intact until a request is made with the agency to withdraw its marketing application for the drug and a notice is published in the Federal Register acknowledging the withdrawal.

Shionogi now faces monetary penalties for not offering good cause for its failure to pursue the studies. In a recent letter, which was sent by Shionogi to the FDA on May 10, the firm revealed that it intends to submit a protocol within 30 days.