



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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USFDA says no to Ranbaxy's drug for enlarged prostate

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Direct link to the News/Story:-

<http://www.business-standard.com/india/news/usfda-says-no-to-ranbaxy%5Cs-drug-for-enlarged-prostate/87258/on>

Pharma major Ranbaxy Laboratories has failed in getting drug regulator USFDA's approval to launch Tamsulosin Hydrochloride, the medicine used in treating enlarged prostate, in the US.

According to sources, Ranbaxy did not get the approval due to the ongoing controversy related to the company not meeting the good manufacturing practice norms of USFDA.

The Gurgaon-based company had applied for USFDA's approval for launching the drug last year.

When contacted, a Ranbaxy spokesperson said: "We regret that despite our best efforts, we were not able to get an approval for the product and hence will not be in a position to launch the product."

US-based company Impax, meanwhile, today announced the launch of the drug after getting the USFDA's nod. It has got the exclusive marketing rights for a period of 180 days.

According to US laws, any generic firm, which is successful in challenging the patent and gets USFDA's approval, would get an exclusive marketing rights for 180 days in the US market.

In US, the market size of the drug is about \$1.2 billion.