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Osmotica fires another salvo at Sun Pharma's anti-depressant

By Kumar Shankar Roy Jun 13 2010, Bangalore

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Desperate to stop competition from Sun Pharma, India's largest drug-maker by market value, in the lucrative \$1.5-2 billion Venlafaxine HCL extended-release tablets (anti-depressant) segment, US-based Osmotica Pharmaceutical Corp has requested the US Food and Drug Administration (USFDA) to make some crucial changes in the generic drug approval process for the product.

If approved, the new norms will affect all present and future generic drug applications including the one from Sun Pharma, which is Osmotica's lone competitor in the Venlafaxine HCL extended-release tablets market. Sun Pharma's Abbreviated New Drug Application (ANDA) for this drug has been lying with FDA for sometime now, leaving Osmotica with room to fire another salvo.

"Osmotica requests that FDA refrain from approving any ANDA for a generic version of Osmotica's Venlafaxine HCL extended-release tablets unless such application contains results from bioequivalence studies conducted under both fed and fasting conditions demonstrating bioequivalence to the reference-listed drug," Mark S Aikman, vice-president, Osmotica Pharmaceutical, wrote in the new citizen petition (CP). The reference-listed drug is the tablet sold by Osmotica, which was first launched in September 2008.

Interestingly, FDA's current draft bioequivalence guidance on Venlafaxine HCL extended-release tablets does not recommend against conducting such studies in the fasting state due to safety concerns. This means that Sun Pharma did not file its product in conformity with Osmotica's new demand and if Osmotica is lucky with FDA, this may require Sun to submit its application once again.

A Sun Pharma spokesperson said it would be difficult to predict when FDA approval for its product would come but said it will launch the product as soon as approval comes. "We have done everything as required by the FDA guidance...instead of speculating (on submitting a new ANDA), it is better we wait for FDA's decision on the CP (filed by Osmotica)," said the official.

Guidance from the Sun Pharma management indicates a strong 18-20 per cent top line growth in FY11, which many analysts believe includes upsides from Venlafaxine HCL extended-release tablets. "Osmotica could have asked about this issue two years ago in the first CP they filed in May 2008, and did not have to wait till May 2010," said a senior pharma analyst with a foreign brokerage.

In the past, Osmotica has filed different citizen's petitions for the same product, aimed at slowing down Sun Pharma's progress on the product's drug approval. However, Sandy Walsh, an FDA official, said that the drug regulator may not delay approval of a pending drug application because of a request unless FDA determines that a delay is necessary to protect the public health. FDA is supposed to respond to a CP in 180 days or provide a tentative response within that time frame but seldom does so.