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Sun Pharma arm suffers US jolt

OUR SPECIAL CORRESPONDENT

Mumbai, Sept. 26: In a setback to Sun Pharma Advanced Research Company (SPARC), the US Food and Drug Administration (USFDA) has revoked an approval for its anti-epileptic drug because of manufacturing quality concerns at the Halol plant of Sun Pharmaceutical Industries.

SPARC is the research & development arm of Sun Pharma and it has plans to manufacture the drug at the Halol facility. It may be recalled that the US drug regulator had earlier observed certain current good manufacturing practices (cGMP) deviations at the unit.

SPARC had received a final approval from the USFDA in March this year for the product and it was evaluating several marketing partners for the product.

However, in a communication to the bourses today, the company said that the US drug regulator has issued a complete response letter to its new drug application for the anti-epileptic drug, indicated for adjunctive therapy in the treatment of partial onset seizures in patients 12 years of age and older with epilepsy.

"SPARC has now received a letter from the USFDA rescinding its earlier approval, citing that the compliance status of the manufacturing facility was not acceptable on the date of approval," it said.

Under the USFDA website, complete response letters are issued when communicating a decision to a drug company that its new drug application or abbreviated new drug application to market a new or generic drug will not be approved in its present form.

SPARC said Sun Pharma is working with USFDA in resolving the cGMP deviations at the facility and has taken several corrective measures.

In a presentation this June, SPARC had said that the market for the drug in the US is at 720 million units and is growing at 5 year compounded annual growth rate (CAGR) of 9 per cent. It had forecast that opportunity exists to market Elepsia XR at significant premium to generics. Commercialisation of the drug in the US market was slated in the second half of this fiscal.

Under new regulations, USFDA's Center for Drug Evaluation and Research (CDER) no longer issues "approvable" or "not approvable" letters when a drug application is not approved. Instead, CDER issues a "complete response" letter at the end of the review period to let a drug company know of the agency's decision on the application.

DRUG APPROVAL REVOKED

Who?
- SPARC: R&D arm of Sun Pharma

What?
- USFDA has revoked an approval for SPARC's anti-epileptic drug

Why?
- Manufacturing quality concerns at Halol plant of Sun Pharma where the drug was to be manufactured

Regulatory