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Sun Pharma cancer drug to address shortage

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Sun Pharma cancer drug approval by US FDA to address shortage

Singapore: The US Food and Drug Administration has approved the first generic version of the cancer drug Doxil (doxorubicin hydrochloride liposome injection) made by Indian generics drug maker Sun Pharma.

Doxorubicin hydrochloride liposome injection is currently on the FDA's drug shortage list. For products on the shortage list, the FDA's Office of Generic Drugs is using a priority review system to expedite the review of generic applications to help alleviate shortages. Doxorubicin hydrochloride liposome injection is administered intravenously by a health care professional. Sun's generic will be available in 20 milligram and 50 milligram vials.

"The agency is committed to doing everything we can to address drug shortages so that patients can get the medicines they need when they need them," said Capt Valerie Jensen, director, Drug Shortage Staff, Center for Drug Evaluation and Research, FDA. "For the past year, the FDA has been working to ensure that supplies of doxorubicin HCl liposome injection were not interrupted."

Generic drugs approved by the FDA have the same high quality and strength as brand-name drugs. The generic manufacturing and packaging sites need to pass the same quality standards as those of brand-name drugs.

In February 2012, to address the shortage of doxorubicin hydrochloride liposome injection, the FDA announced it would exercise enforcement discretion for temporary controlled importation of Lipodox (doxorubicin hydrochloride liposome injection), an alternative to Doxil produced by Sun and its authorized distributor, Caraco Pharmaceutical that is not approved in the US. Enforcement discretion was also used to release one lot of Janssen's Doxil made under an unapproved manufacturing process.

Presently, FDA intends to continue exercising enforcement discretion for importation of Lipodox, and limited supplies of Doxil are available. Once supplies of Sun's generic doxorubicin hydrochloride liposome injection are sufficient to meet projected demand, FDA expects to stop exercising enforcement discretion for any unapproved doxorubicin HCl liposomal product.