

Hoping to ease shortage, FDA fast-tracks generic form of cancer drug

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Agency says new availability of doxorubicin will help people battling malignancy.

(HealthDay)—Seeking to ease potentially dangerous shortages of a key cancer drug, the U.S. Food and Drug Administration on Monday announced it had fast-tracked the approval of the first generic form of one such medication, Doxil (doxorubicin).

"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," Capt. Valerie Jensen, director of the Drug Shortage Staff at the FDA's Center for [Drug Evaluation](#) and Research, said in an agency news release. "For the past year, the FDA has been working to ensure that supplies of [[doxorubicin](#)] were not interrupted."

The new [generic version](#) is made by Sun Pharma Global and will be available in 20 milligram and 50 milligram vials. Like brand-name Doxil, the injected drug is administered intravenously by a health care

professional.

[Generic drugs](#) approved by the FDA have the same quality and strength as brand name drugs, and the generic manufacturing and packaging sites must pass the same quality standards as those of brand name drugs, the agency noted.

In response to the Doxil shortage, the FDA announced in February 2012 that it would allow temporary controlled importation of Lipodox, an alternative to Doxil that is produced by Sun Pharma Global but not approved in the United States.

The FDA also decided to allow the release of one lot of Janssen's Doxil made under an unapproved manufacturing process.

For the time being, the FDA said it will continue to allow the controlled importation of Lipodox. Once there is enough of Sun's generic version to meet projected demand, the FDA will halt imports of any unapproved doxorubicin product.

Shortages of potentially life-saving cancer medications have plagued the U.S. [health care system](#) for the past two years.

Speaking at the annual meeting of the American Society for Clinical Oncology last June, Dr. Richard Schilsky, chair of ASCO's government relations committee, told reporters that some shortages had eased, "but there is still an unpredictable availability of many drugs and we are never sure exactly when a generic drug is suddenly going to go out of supply."

According to Schilsky, "that creates a tremendous amount of uncertainty—*anxiety for our patients and great difficulty in planning if you're a physician.*"

In October of 2011, President Barack Obama signed a special Executive Order demanding action on the issue, which is often caused by interruptions in manufacturing as companies address safety issues.

Besides Doxil, other drugs that have seen interruptions in supply include nitrogen mustard (used to fight blood cancers), paclitaxel (important for breast cancer and other tumors), 5-FU (used in a variety of cancers), and methotrexate (important to treat certain lymphomas).

More information: The U.S. Food and Drug Administration has more about [drug shortages](#).

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