FDA Approves Generic Version of Cancer Drug

Health regulators have approved a generic version of the cancer drug Doxil in a move that could ease a months-long shortage that has threatened the lives of thousands of patients.

The Food and Drug Administration said on Monday it approved a version of Doxil, known generically as doxorubicin HCI liposome injection, that is made by Sun Pharma Global FZE, a subsidiary of India's Sun Pharmaceutical Industries Ltd. It will be available in 20 milligram and 50 milligram vials.

Sun's product is the first generic version of Doxil, which was approved in 1995 and is used to treat ovarian cancer, AIDS-related Kaposi's sarcoma, and multiple myeloma. Doxil is made by Johnson & Johnson.

Doxil fell into short supply after manufacturing problems at an outside contract manufacturer, Ben Venue Laboratories Inc, a unit of German drugmaker Boehringer Ingelheim, suspended operations in November 2011 due to quality control problems.

Last February, the FDA allowed for the temporary importation of Lipodox, which is made by Sun and contains the same active ingredient as Doxil. The agency said it intends to continue allowing the importation of Lipodox until Sun has made enough generic Doxil to meet demand.

Late last month a federal judge approved a consent decree under which Ben Venue must bring its Bedford, Ohio facility into compliance with regulatory requirements or face fines and other penalties.

The FDA said the company had repeatedly violated good manufacturing practices. Recent inspections found that poorly

maintained equipment deteriorated to the point that it shed particles into injectable drugs, the FDA said.

President Barack Obama made drug shortages a national priority with an executive order in October, 2011.