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Drugmaker pulls painkillers from US market over heart risks

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Drugmaker Xanodyne Pharmaceuticals Inc. agreed Friday to pull two of its painkillers, Darvon and Darvocet, from the US market over heart risk concerns, the US Food and Drug Administration said.

Similar withdrawals from the market of the drug also known as propoxyphene were recommended in Europe in 2009 and are already under way.

"The FDA sought market withdrawal of propoxyphene after receiving new clinical data showing that the drug puts patients at risk of potentially serious or even fatal heart rhythm abnormalities," the agency said.

"As a result of these data, combined with other information, including new epidemiological data, the agency concluded that the risks of the medication outweigh the benefits."

Generic manufacturers of the medication were also notified of Xanodyne's decision and urged to do the same, the FDA said.

The European Medicines Agency recommended in 2009 that "marketing authorizations for propoxyphene be withdrawn across the European Union. A phased withdrawal of propoxyphene is underway," the FDA noted.

Propoxyphene, an opioid used to treat mild to moderate pain, has been on the US market since it was first approved by the FDA in 1957.

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