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## News & Events

### FDA NEWS RELEASE

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#### **Xanodyne agrees to withdraw propoxyphene from the U.S. market**

Xanodyne Pharmaceuticals Inc. which makes Darvon and Darvocet, the brand version of the prescription pain medication propoxyphene, has agreed to withdraw the medication from the U.S. market at the request of the U.S. Food and Drug Administration. The FDA has also informed the generic manufacturers of propoxyphene-containing products of Xanodyne's decision and requested that they voluntarily remove their products as well.

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. 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.

"The FDA is pleased by Xanodyne's decision to voluntarily remove its products from the U.S. market," said John Jenkins, M.D., director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research (CDER). "These new heart data significantly alter propoxyphene's risk-benefit profile. The drug's effectiveness in reducing pain is no longer enough to outweigh the drug's serious potential heart risks."

The FDA is advising health care professionals to stop prescribing propoxyphene to their patients, and patients who are currently taking the drug should contact their health care professional as soon as possible to discuss switching to another pain management therapy.

Propoxyphene is an opioid used to treat mild to moderate pain. First approved by the FDA in 1957, propoxyphene is sold by prescription under various names both alone (e.g., Darvon) or in combination with acetaminophen (e.g., Darvocet).

Since 1978, the FDA has received two requests to remove propoxyphene from the market. Until now, the FDA had concluded that the benefits of propoxyphene for pain relief at recommended doses outweighed the safety risks of the drug.

In January 2009, the FDA held an advisory committee meeting to address the efficacy and safety of propoxyphene. After considering the data submitted with the original drug applications for propoxyphene, as well as subsequent medical literature and postmarketing safety databases, the committee voted 14 to 12 against the continued marketing of propoxyphene products. In making this recommendation, the committee noted that additional information about the drug's cardiac effects would be relevant in weighing its risks and benefits.

In June 2009, the European Medicines Agency (EMA) recommended that the marketing authorizations for propoxyphene be withdrawn across the European Union. A phased withdrawal of propoxyphene is underway.

In July 2009, the FDA decided to permit continued marketing, but required that a new boxed warning be added to the drug label alerting patients and health care professionals to the risk of a fatal overdose. In addition, the agency required Xanodyne to conduct a new safety study assessing unanswered questions about the effects of propoxyphene on the heart.

The agency now has reviewed the data from that study, which show that, even when taken at recommended doses, propoxyphene causes significant changes to the electrical activity of the heart. These changes, which can be seen on an electrocardiogram (ECG), can increase the risk for serious abnormal heart rhythms that have been linked to serious adverse effects, including sudden death. The available data also indicate that the risk of adverse events for any particular patient (even patients who have taken the drug for many years) is subject to change based on small changes in the health status of the patient, such as dehydration, a change in medications, or decreased kidney function.

"With the new study results, for the first time we now have data showing that the standard therapeutic dose of propoxyphene can be harmful to the heart," said Gerald Dal Pan, M.D., M.H.S., director of the Office of Surveillance and Epidemiology, CDER. "However, long-time users of the drug need to know that these changes to the heart's electrical activity are not cumulative. Once patients stop taking propoxyphene, the risk will go away."

Xanodyne is based in Newport, Ky.



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