FDA orders overdose warnings for Darvocet

July 7 2009, By LAURAN NEERGAARD , AP Medical Writer

(AP) -- The government is letting the painkillers Darvocet, Darvon and their generic cousins stay on the market but ordered stronger warnings against deadly overdoses on Tuesday.

The Food and Drug Administration's decision puts the U.S. in stark contrast to Britain - which banned the drugs several years ago, citing a trail of suicides and accidental overdoses - and Europe's drug regulators, which just recommended that European Union countries do the same.

Known generically as propoxyphene, the 50-year-old prescription drug is widely used in the U.S. even though doctors consider it a weak pain reliever. The consumer watchdog group Public Citizen had petitioned the FDA to ban it here, too, saying the small benefit didn't justify a risk that was adding up to several hundred deaths a year. In January, the FDA's scientific advisers narrowly agreed.

But the FDA overruled its advisers Tuesday, at least for now. It ordered that a stern boxed warning be placed on the drug's label, and that patients soon start receiving a special pamphlet with every bottle that stresses the risk of taking too much.

Also Tuesday, FDA ordered manufacturer Xanodyne Pharmaceuticals Inc. of Newport, Ky., to study the effect of higher-than-recommended doses on patients' hearts, saying the findings could lead to additional actions. And the agency is seeking help from Medicare and the Department of Veterans Affairs to further study the drug's specific effects in the elderly.

For now, FDA decided "this is an acceptable option for patients," said agency drug chief Dr. Janet Woodcock, stressing that other painkillers come with their own sets of side effects.

Indeed, just last week another panel of FDA's advisers warned against liver damage from overdoses of over-the-counter acetaminophen, the painkiller in Tylenol and numerous other drug brands - and the agency is considering restrictions on that drug, too.

As for Darvon and Darvocet, Public Citizen is considering whether to appeal FDA's decision or to sue over it.

"This is a reckless decision on the part of the FDA unless they believe Americans are resistant to the death-causing properties of this drug in a way that Europeans and people in the U.K. aren't," said Public Citizen's Dr. Sidney Wolfe. "You've got a drug which has a barely perceptible benefit and a very clear risk."

A large enough dose of many pain relievers can kill, making it hard to use medication regulation to guard against suicide.

But Wolfe worries about longtime Darvon and Darvocet users who inch up their dose in hopes of better pain relief. A heart-toxic metabolite of the drug can linger in the body for 30 hours, so as little as one or two extra pills each time a dosage is due could quickly add up to damaging levels, Wolfe said. Too much can eventually interrupt the heart's electrical activity, a deadly condition known as heart block, he said.

By the FDA's count, about 21 million prescriptions were written for propoxyphene-containing drugs in 2007. Most popular is Darvocet or its generic equivalent, which combines the narcotic propoxyphene with the more common painkiller acetaminophen. At FDA's January meeting on the drug, officials cited studies showing most of the pain relief from

Darvocet came from the acetaminophen component.

Wolfe cited data from the government's Drug Abuse Warning Network, which tracks emergency room visits, that counted 503 Darvon-related deaths in 2007, about 20 percent of them classified as suicides.

Britain phased the drug off the market, between 2005 and the end of 2007, to give patients time to switch to other painkillers. A recent study in the British Medical Journal tracked a drop in propoxyphene-related deaths as prescriptions plummeted during that period, and researchers calculated that 349 deaths were prevented.