FDA acts against unapproved colchicine

6 February 2008

The U.S. Food and Drug Administration said it will take action against companies marketing unapproved injectable colchicine, a drug used to treat gout.

Colchicine is a highly toxic drug that can easily be administered in excessive doses, especially when given intravenously, the FDA said, noting there's only a narrow margin between an effective dose of the drug and a toxic, perhaps even fatal, dose.

Officials said they had received 50 reports of adverse events associated with the use of intravenous colchicine, including 23 deaths.

"Today's action supports our ongoing efforts to end the marketing of unapproved drugs with serious health risks," said Dr. Janet Woodcock, the FDA's deputy commissioner for scientific and medical programs. "It is a priority that these products be removed from the market."

The FDA warned individuals and companies making the products to cease their activities within 30 days and stop shipping the product within 180 days or face regulatory action. Thereafter, all injectable colchicine drug products must have FDA approval to be manufactured or shipped interstate.

The FDA said its action announced Thursday does not affect colchicine products that are dispensed in tablet form and are frequently used to prevent gout attacks.