

## FDA tells doctors new heparin formula less potent

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(AP) -- The Food and Drug Administration is alerting doctors that a widely used blood thinner has been reformulated to improve its safety, though the change could open the door to dosing errors.

The FDA said Thursday new heparin vials scheduled to begin shipping next week will be 10 percent less potent than the original blood thinner. The change is designed to make it easier for manufacturers to spot impurities in the drug, but it will require some adjustments by physicians who administer the drug.

"Health care providers should consider the change in potency of heparin when making decisions about which dose to administer," said Dr. John Jenkins, director of the FDA's office of new drugs. Doctors may need to use extra heparin to adequately treat some patients, he added.

The FDA said older vials of heparin will remain on the market after the new formula begins shipping Oct. 8. While having both on the market could cause confusion, the agency said it was necessary to ensure there is adequate supply of the drug.

U.S. Pharmacopeia, a nonprofit that defines standards for U.S. pharmaceuticals, set the new heparin formula guidelines.

Last year, contaminated heparin imported from China was linked to hundreds of life-threatening [allergic reactions](#) and more than 200 deaths. The drug was recalled by Baxter International and the U.S. blocked

imports from the Chinese company that supplied the main ingredient.

The FDA determined that the heparin was contaminated with a nutritional supplement that costs less, but mimics the real drug in routine tests for potency. Agency inspectors suspected deliberate contamination.

Heparin, derived from a chemical in pig intestines, is used in [heart surgery](#), kidney dialysis and a variety of other medical procedures.

Most manufacturers of the drug will place an 'N' on the label of the new formulas to help health care providers tell the difference.

The four producers of [heparin](#) in the U.S. are APP Pharmaceuticals, Hospira, Baxter and B.Braun.

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