



The Florida ESRD Network

FDA Alert - New USP Standards for Heparin Products

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The U.S. Food and Drug Administration today alerted health care professionals to a change in heparin manufacturing that is expected to decrease the potency of the common blood-clotting drug. To ensure the quality of heparin and to guard against potential contamination, the United States Pharmacopeia (USP), a nonprofit standards-setting organization, adopted new manufacturing controls for heparin. These changes include a modification of the reference standard for the drug's unit dose.

Manufacturers in the United States label the amount of heparin included in their products based on USP standards. The changes adopted by the USP for the heparin unit dose match the World Health Organization's International Standard (IS) unit dose definition that has been in use in Europe for many years. The revised USP reference standard and unit definition for heparin is about **10 percent less potent** than the former USP unit.

Manufacturers for the U.S. market have begun to make heparin using the new USP standard. While the USP manufacturing controls take effect Oct. 1 for production, the FDA has asked that they not ship this new product to customers until Oct. 8, 2009, or later. The delay will give health care providers and facilities time to learn about the changes, become aware of the potential difference in potency between the old and new vials of heparin, and make adjustments to their pharmacy procedures and dosing practices.

For more information

FDA Alert to Health Care Professionals

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm184502.htm>

USP Heparin Information

<http://www.usp.org/hottopics/heparin.html>

Information for Consumers: What You Should Know about Changes to Heparin

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm184504.htm>

The Florida ESRD Network (Network 7) is providing this fax blast as a
Technical assistance activity for the Florida renal community.

FMQAI: The Florida ESRD Network
5201 West Kennedy Boulevard, Suite 900 • Tampa, Florida 33609
813-383-1530 • 813-354-1514 Fax