

This update is being distributed to local public health departments, hospitals (Infection Control and Administration), Primary Care Providers, Hematology, Emergency Room Physicians, Infectious Disease and Dialysis. It may be further distributed and posted as necessary.

Dear Colleague,

Please help the Food and Drug Administration (FDA) spread the word about recalls of injectable heparin products and heparin flush solutions that may be contaminated with oversulfated chondroitin sulfate (OSCS). Affected heparin products have been found in medical care facilities in one state since the recall announcement. Although product recall instructions were widely distributed, they may not have been fully acted upon at all sites where heparin is used. There have been many reports of deaths associated with allergic or hypotensive symptoms after heparin administration (see FDA link at:

http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm).

We ask that health professionals and facilities please review and examine all drug/device storage areas, including emergency kits, dialysis units and automated drug storage cabinets to ensure that all of the recalled heparin products have been removed and are no longer available for patient use. In addition, FDA would like to inform health professionals about other types of medical devices that contain, or are coated with, heparin.

To read this update, and to learn how to report these problems to FDA, please go to: <http://www.fda.gov/cdrh/safety/heparin-healthcare-update.html>. Please report to FDA adverse reactions associated with these devices, as well as any reactions associated with heparin or heparin flush solutions. If you have questions or would like more information about this request, please contact the Division of Drug Information at 301-796-3400.

We apologize in advance if you receive multiple copies of this information. Thank you for your ongoing support of FDA activities.

Sincerely,

*Janelle Derbis, PharmD
Office of Special Health Issues
U.S. Food and Drug Administration
20 N. Michigan Avenue, Suite 510
Chicago, IL 60602
(312) 596-6516
(312) 886-1682 (fax)
Janelle.derbis@fda.hhs.gov*

*Brenda L. Evelyn, SBB(ASCP)
Office of Special Health Issues
U.S. Food and Drug Administration
5600 Fishers Lane, Room 9-49
Rockville, MD 20857
(301) 827-4460
(301) 443-4555 (fax)
Brenda.evelyn@fda.hhs.gov*