Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 12, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Hospira, Inc. – RECALL [Drug]

AFFECTED PRODUCT: **Heparin Sodium, 1,000 USP Heparin Units/500 mL (2 USP Heparin Units/mL), in 0.9% Sodium Chloride Injection, 500 mL**

SUMMARY: **Unclassified Recall; The recall is due to one confirmed customer report of particulate matter in a single unit.**

Heparin Sodium, 1,000 USP Heparin Units/500 mL (2 USP Heparin Units/mL), in 0.9% Sodium Chloride Injection, 500 mL, NDC 0409-7620-03 Lot 41-046-JT with expiration date of 01NOV 2015.

The affected lot was distributed nationwide between June 2014 and August 2014 to wholesalers/distributors, hospitals and pharmacies.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-855-201-4337 between the hours of 8am to 5pm ET, Monday through Friday.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Hospira Issues a Voluntary Nationwide Recall of One Lot of Heparin Sodium, 1,000 USP Heparin Units/500 mL (2 USP Heparin Units/mL),

In 0.9% Sodium Chloride Injection, 500 mL, Due to Particulate Matter

Contact:
Consumer:
1-800-615-0187

Media:
224-212-2357

FOR IMMEDIATE RELEASE - Sept. 11, 2014 - LAKE FOREST, Ill., - Hospira, Inc. (NYSE: HSP), announced today it is initiating a voluntary nationwide user-level recall of one lot of Heparin Sodium, 1,000 USP Heparin Units/500 mL (2 USP Heparin Units/mL), in 0.9% Sodium Chloride Injection, 500 mL, NDC 0409-7620-03 Lot 41-046-JT with expiration date of 01NOV 2015. This action is due to one confirmed customer report of particulate in a single unit. The foreign particle was confirmed by Hospira as human hair, sealed between the tube and the film at the round seal of the unused Administrative Port on the non-print side of the container.

In the unlikely event that the particulate breaks and pieces are able to pass through the intravenous catheter, injected particulate material may result in local inflammation, phlebitis, and/or low-level allergic response. Capillaries which may be as small as the size of a red blood cell, approximately seven microns in diameter, may become occluded. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk.

Heparin Sodium Injection in 0.9% Sodium Chloride at a concentration of 2 units/mL is indicated as an anticoagulant to maintain catheter patency. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. The root cause has not been determined and is under investigation.

The affected lot was distributed nationwide between June 2014 and August 2014 to wholesalers/distributors, hospitals and pharmacies.

Anyone with an existing inventory should stop use and distribution and quarantine the product immediately. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira will be notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle. For additional assistance, call Stericycle at 1-855-201-4337 between the hours of 8am to 5pm ET, Monday through Friday.

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (8am-5pm CT, M-F)(ProductComplaintsPP@hospira.com)	To report adverse events or product complaints

Hospira Contact	Contact Information	Areas of Support
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days per week)	Medical inquiries

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Hospira
Hospira, Inc. is the world's leading provider of injectable drugs and infusion technologies, and a global leader in biosimilars. Through its broad, integrated portfolio, Hospira is uniquely positioned to Advance Wellness™ by improving patient and caregiver safety while reducing healthcare costs. The company is headquartered in Lake Forest, Ill., and has approximately 17,000 employees. Learn more at www.hospira.com.

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