Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: December 26, 2013

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

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Hospira, Inc. [Drug]

AFFECTED PRODUCT: **One lot of Lidocaine HCl Injection, USP, 2%, 5 mL Single-Dose Vial (NDC 0409-2066-05), Lot 32-135-DD, expiration date 1AUG2015.**

SUMMARY: **Unclassified Recall; The recall is due to a reddish orange particulate on the inner surface and floating in the solution.**

The recalled lot was distributed to distributors/wholesalers, hospitals, and pharmacies nationwide and more specifically *Indiana, Ohio, Kentucky, Illinois, and Michigan* between September 2013 through October 2013.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-855-695-8596 between 8 a.m. and 5 p.m., 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 Lidocaine HCl Injection, USP, 2%, 5 Ml in 5 Ml Vial, Due to Presence of Particulate Matter

Contact
Consumer:
1-855-695-8596

Media:
224-212-2357

FOR IMMEDIATE RELEASE - December 23, 2013 - Hospira, Inc. (NYSE: HSP), announced today it will initiate a voluntary nationwide recall to the user level for one lot of Lidocaine HCl Injection, USP, 2%, 5 mL Single-Dose Vial (NDC 0409-2066-05), Lot 32-135-DD, expiration date 1AUG2015. The recall is due to a reddish orange particulate on the inner surface and floating in the solution.

If particulate goes undetected and solution is administered, the particle may potentially block the infusion of the solution to the patient, resulting in a delay in therapy. If smaller pieces of the particulate break off and become free floating within the solution, they may pass through the catheter into the patient, resulting in local inflammation or mechanical disruption of tissue. Chronically, following sequestration, local granuloma formulation is possible. In consideration of the reddish orange color of the particulate, if there is iron within the particle that is infused, it may put a patient at risk when undergoing MRI (strong magnetic field exposure), as the particle could potentially be dislodged and be pulled through tissue, causing local inflammation and tissue trauma.

Lidocaine is packaged 10 units per carton/180 units per case in single dose glass fliptop vials.

The recalled lot was distributed to distributors/wholesalers, hospitals, and pharmacies located in AL, AZ, CA, CO, FL, GA, HI, IL, IN, KY, LA, MD, MA, MI, MS, MO, NV, NJ, NC, OH, OK, PA, TN, TX, UT, VA, WA, and WI between September 2013 through October 2013. Hospira became aware of the issue after receiving a complaint of particles in the glass vial. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. Hospira believes the embedded particulate is related to a supplier's glass defect.

Anyone with an existing inventory should immediately stop use and quarantine any affected product and return the product to Stericycle. Hospira will be notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle for returns processing. For additional assistance, call Stericycle at 1-855-695-8596 between 8 a.m. and 5 p.m., 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 Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days per week)	Medical inquiries

Any adverse reactions or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Events Program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular mail:** use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/MedWatch/getforms.htm
- **Fax:** 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. 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 16,000 employees. Learn more at www.hospira.com.

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