Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: April 21, 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: **1% Lidocaine HCl Injection, USP**

SUMMARY: **Unclassified Recall; The recall is due to orange and black particulate within the solution and embedded within the glass vial.**

The lot number affected by the recall is:

Product	NDC Number	Lot	Expiration Date
1% Lidocaine HCl Injection, USP, 10mg/mL, 30 mL single dose, Preservative - Free	0409-4279-02	31-427-DK	1JUL2015

This lot was distributed nationwide to distributors/wholesalers, hospitals and clinics from September 2013 through October 2013.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-888-835-2723 (M-F, 8 a.m. - 5 p.m. ET).**

****

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 Announces Voluntary Nationwide Recall of One Lot of 1% Lidocaine HCI INjection, USP, Due To Visible Particulates

Contact:
Consumer:
1-800-615-0187

Media:
224-212-2357

FOR IMMEDIATE RELEASE - April 18, 2014 - Hospira, Inc. (NYSE: HSP), announced today it will initiate a voluntary recall of one lot of 1% Lidocaine HCI Injection, USP to the user level due to a confirmed customer report of orange and black particulate within the solution and embedded within the glass vial. Hospira has identified the particulate as iron oxide. Risk factors associated with the particulate include the potential for particulate to be injected and/or a delay in therapy.

If the particulate or smaller pieces of the particulate that could break off, become free floating within the solution pass through the catheter into the patient, it may result in local inflammation, and/or mechanical disruption of tissue or immune response to the particulate. Chronically, following sequestration, local granuloma formulation may occur.

This lot was distributed nationwide to distributors/wholesalers, hospitals and clinics from September 2013 through October 2013. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. The lot number affected by the recall is:

Product	NDC Number	Lot	Expiration Date
1% Lidocaine HCI Injection, USP, 10mg/mL, 30 mL single dose, Preservative - Free	0409-4279-02	31-427-DK	1JUL2015

Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Anyone with existing inventory should immediately stop use and quarantine any affected product. 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 returns processing. For additional assistance, call Stericycle at 1-888-835-2723 (M-F, 8 a.m. - 5 p.m. ET).

For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187. This phone number is available 24 hours a day, seven days a week.

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

###