Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 20, 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 for Injection, USP, 10 mg per mL, 30 mL Single-dose, Preservative-Free**

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

The recalled product is one lot of 1% Lidocaine HCl for Injection, USP, 10 mg per mL, 30 mL Single-dose, Preservative-Free (NDC 0409-4279-02; Lot 40-316-DK, Expiry 1APRIL2016).

This lot was distributed nationwide from May 2014 through June 2014.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-877-546-5069 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 Announces Voluntary Nationwide Recall Of One Lot Of 1% Lidocaine HCl Injection, USP 10 MG Per ML, 30 ML Single-Dose. Preservative-Free, Due To Particulate Matter

Contact
Consumer:
1-800-615-0187

FOR IMMEDIATE RELEASE - October 16, 2014 - LAKE FOREST, Ill., - Hospira, Inc. (NYSE: HSP), announced today it will initiate a voluntary recall of one lot of 1% Lidocaine HCl for Injection, USP, 10 mg per mL, 30 mL Single-dose, Preservative-Free (NDC 0409-4279-02; Lot 40-316-DK, Expiry 1APRIL2016) to the user level due to a confirmed customer report of particulate in a single unit. Hospira has identified the particulate as a human hair, embedded in and attached to a pinched area of the stopper. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

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 to the particulate or microembolic effects. If the solution with particulate is administered via caudal or lumbar epidural route using appropriate technique, particulate material injected into the epidural space may result in local inflammation, mechanical disruption of tissue, or immune response to the particulate

This lot was distributed nationwide from May 2014 through June 2014. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. This recall is being carried out to the medical facility/retail level (both human and veterinary). Please notify all users in your facility. If you have further distributed the recalled product please notify any accounts or additional locations which may have received the recalled product from you and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the medical facility/retail level. In addition, customers should inform potential users of these products in their organizations of this notification. Hospira will be notifying its direct customers via a recall letter and will arrange for impacted product to be returned to Stericycle. For additional assistance, call Stericycle at 1-877-546-5069 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 (M-F, 8am to 5pm CT) (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

Adverse reactions or quality problems experienced with the use of the 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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