Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 17, 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, Expanded Recall [Drug]

AFFECTED PRODUCT: **0.25% Bupivacaine HCl Inj., USP (2.5 mg/mL), 30 mL Single-dose Vial, NDC # 0409-1159-02, Lot # 18-136-DK*, expires 1JUN2014.**
0.75% Bupivacaine HCl Inj., USP (7.5 mg/mL), 30 mL Single-dose Preservative-Free Vial, NDC # 0409-1165-02, Lot # 23-338-DK, expires 1NOV2014.

SUMMARY: **Unclassified Recall; Hospira, Inc. (NYSE: HSP), originally initiated a voluntary nationwide recall July 12, 2013 to the user level for one lot of 0.25% Bupivacaine HCl Injection, USP (2.5 mg/mL), 30 mL Single-dose Vial (NDC 0409-1159-02). The recall was expanded on August 29, 2013 to include one lot of 0.75% Bupivacaine HCl Injection, USP (7.5 mg/mL), 30 mL Single-dose Vial (NDC 0409-1165-02). Both recalls are due to confirmed customer reports of particulate floating and/or embedded in the glass vial. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. Lot 18-136-DK was distributed August 2012 through September 2012. Lot 23-338-DK was distributed January 2013 through May 2013. Both lots were distributed nationwide to wholesalers/distributors, hospitals and pharmacies.**

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail. Be aware of this recall in case of consumer concern. Direct all consumers to contact their physicians or healthcare providers if they experience problems associated with this product. Anyone with an existing inventory should immediately quarantine any affected product and return the product to Stericycle. For additional assistance, call Stericycle at: 1-866-240-5364 for 18-136-DK; and 1-888-627-2279 for 23-338-DK. Furthermore, if any recalled products are found contact this office at 317-233-3213.**

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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 0.25% Bupivacaine HCL Injection, USP (2.5 MG/ML), 30 ML Single-Dose Vial and One Lot of 0.75% Bupivacaine HCL Injection, USP (7.5 MG/ML), 30 ML Single Dose Vial Due to Presence of Particulate Matter

Contact:
Media
(224) 212-2357

FOR IMMEDIATE RELEASE - Sept. 13, 2013 - LAKE FOREST, Ill., - Hospira, Inc. (NYSE: HSP), announced today, on July 12, 2013, it initiated a voluntary nationwide recall to the user level for one lot of 0.25% Bupivacaine HCl Injection, USP (2.5 mg/mL), 30 mL Single-dose Vial (NDC 0409-1159-02). An expanded recall was issued on August 29, 2013 for one lot of 0.75% Bupivacaine HCl Injection, USP (7.5 mg/mL), 30 mL Single-dose Vial (NDC 0409-1165-02). Both recalls are due to confirmed customer reports of particulate floating and/or embedded in the glass vial. The particulate was identified as stainless steel ranging in size from 542 microns to 1700 microns in lot 18-136-DK (0.25% bupivacaine) and as iron oxide with an average size of 2000 microns in lot 23-338-DK (0.75% bupivacaine). To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

Both products are packaged 25 units per carton/50 units per case in glass teartop vials.

Bupivacaine is indicated for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures.

The administration of an injectable with the presence of foreign particulates may potentially cause thrombophlebitis, bacteremia, sepsis, and/or endocarditis and death may result. Signs and symptoms could include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea and vomiting. Depending on the particle size, if undetected, it could block administration of the diluted drug to the patient, causing a delay in therapy.

Lot 18-136-DK was distributed August 2012 through September 2012. Lot 23-338-DK was distributed January 2013 through May 2013. Both lots were distributed nationwide to wholesalers/distributors, hospitals and pharmacies.

Product	NDC Number	Lot	Expiration Date
0.25% Bupivacaine HCl Inj., USP (2.5 mg/mL), 30 mL Single-dose Vial	0409-1159-02	18-136-DK*	1JUN2014

0.75% Bupivacaine HCl Inj., USP (7.5 mg/mL), 30 mL Single-dose Preservative-Free Vial	0409-1165-02	23-338-DK*	1NOV2014

Anyone with an existing inventory should immediately quarantine any affected product and return the product to Stericycle. For additional assistance, call Stericycle at:

Lot	Phone Number (8am to 5pm ET, M-F)
18-136-DK	1-866-240-5364
23-338-DK	1-888-627-2279

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[1]
- **Regular mail:** use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/MedWatch/getforms.htm[2]
- **Fax:** 1-800-FDA-0178

This recall is being conducted with the knowledge of the FDA.

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[3].

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