Indiana State Department of Health
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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: **Propofol Injectable Emulsion, USP**

SUMMARY: **Unclassified Recall; The recall is due to a glass defect located on the interior neck of the vial, where the glass vial contained visible embedded metal particulate. Free-floating metal particulates were also identified in the vials.**

The lot numbers affected by the recall are:

Product	*NDC Number*	*Lot*	*Expiration Date*
Propofol Injectable Emulsion, 1%, 200 mg / 20 mL (10 mg/mL)	0409-4699-30	29-614-DJ	1MAY2015
		29-615-DJ	1MAY2015
		29-616-DJ	1MAY2015
		29-617-DJ	1MAY2015
		29-628-DJ	1MAY2015
		29-629-DJ	1MAY2015
		29-630-DJ	1MAY2015

The affected lots were distributed nationwide to distributors/wholesalers, hospitals and clinics from August 2013 through December 2013.

SUGGESTED ACTION: **For consumer inquiry only. Customers have been advised to check inventory and immediately quarantine any affected product. In addition, customers should inform potential users of this product in their organizations of this notification. Affected product should be returned to Stericycle, which can be contacted at 1-877-272-2158 (M-F, 8 a.m. - 5 p.m. ET).**

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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 Nationwide Voluntary Recall of Seven Lots of Propofol Injectable Emulsion, USP, Due to Visible Particulates

Contact:
Consumer:
1-877-272-2158

Media:
224-212-2357

FOR IMMEDIATE RELEASE - April 17, 2014 - Hospira, Inc. (NYSE: HSP), announced today that on April 2, 2014, it informed customers of a nationwide recall of seven lots of Propofol Injectable Emulsion, USP, to the user level due to a glass defect located on the interior neck of the vial, which was identified during a retain sample inspection where the glass vial contained visible embedded metal particulate. Free-floating metal particulates were also identified in vials upon further analysis.

In general, injected particulate matter may result in local inflammation, phlebitis, and/or low level allergic response through mechanical disruption of tissue or immune response to the particulate. Capillaries, which may be as small as the size of a red blood cell, may become occluded. Chronically, following sequestration, particulate matter may lead to granulomatous formation, most likely in the lungs. Long term clinically meaningful impact is low if a patient has normal lung function. While extremely rare, embedded stainless steel may put a patient at risk from MRI (strong magnetic field exposure) as particulate, if in the lung, could potentially dislodge and be pulled through tissue. To date, Hospira has not received reports of any adverse events associated with this issue for these lots.

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		29-617-DJ	1MAY2015
		29-628-DJ	1MAY2015

29-629-DJ 1MAY2015
29-630-DJ 1MAY2015

On April 2, 2014, Hospira notified its customers via recall letter that the company had implemented corrective actions to the manufacturing process to prevent recurrence.

Customers have been advised to check inventory and immediately quarantine any affected product. In addition, customers should inform potential users of this product in their organizations of this notification. Affected product should be returned to Stericycle, which can be contacted at 1-877-272-2158 (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.

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