Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 14, 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: **Lactated Ringers and 5% Dextrose Injection, USP, 1000 mL**

SUMMARY: **Unclassified Recall; The recall is due to one confirmed customer report where particulate was identified within the solution of the primary container. The particulate was identified as a filamentous-like structured particulate indicative of mold.**

The product is Lactated Ringers and 5% Dextrose Injection, USP, 1000 mL, Flexible Container, NDC 0409-7929-09, Lot 35-118-JT, Expiry 1NOV2015 packaged 1 container per overwrap, and 12 overwrapped containers in each case. The lot number is located in the upper left hand side of the primary container.

This lot was distributed nationwide from December 2013 through February 2014 and was distributed to hospitals, clinics, wholesalers and distributors.

SUGGESTED ACTION: **For consumer inquiry only. Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-888-912-8457 between the hours of 8am to 5pm EST, Monday through Friday, to arrange for the return of the product.**

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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 Voluntary Nationwide Recall Of One Lot Of Lactated Ringers And 5% Dextrose Injection, Usp, 1000 ML, Flexible Containers Due To Mold Contamination

Contact:
Consumer:
1-888-912-8457

Media:
224-212-2357

FOR IMMEDIATE RELEASE - July 10, 2014 - Hospira, Inc. (NYSE: HSP), announced today it is initiating a voluntary nationwide user-level recall of one lot of Lactated Ringers and 5% Dextrose Injection, USP, 1000 mL, Flexible Container, NDC 0409-7929-09, Lot 35-118-JT, Expiry 1NOV2015 . This action is due to one confirmed customer report where particulate was identified within the solution of the primary container. The particulate was identified as a filamentous-like structured particulate indicative of mold. Analysis of the primary container and overwrap indicated a puncture in the same physical location, causing the primary container to leak.

Intravenous administration of a non-sterile product can result in infections that may be life-threatening, and may result in prolonged hospitalization or organ failure. Hospira has not received reports of any adverse events associated with this issue for this lot to date, and has not identified any quality issues with retention samples for this lot. Hospira has investigated and determined the root cause of the event and has implemented corrective actions to address this issue.

In general, a defect in a container leading to a leak may create a breach in sterility since an open pathway exists for contamination of fluid. If the leak is not detected, and the solution becomes contaminated and it is not identified prior to administration, there is potential that contaminated solution could be administered to the patient.

The product is indicated for parenteral replacement of extracellular losses of fluid and electrolytes, with or without minimal carbohydrate calories, as required by the clinical condition of the patient. The product is packaged in 1000mL flexible containers, 1 container per overwrap, and 12 overwrapped containers in each case. The lot number is located in the upper left hand side of the primary container. This lot was distributed nationwide from December 2013 through February 2014 and was distributed to hospitals, clinics, wholesalers and distributors. This recall is being conducted as a precautionary measure.

Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-888-912-8457 between the hours of 8am to 5pm EST, Monday through Friday, to arrange for the return of the product.

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (8am-5pm CT, M-F)(medcom@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 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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