Recall of One Lot of Lactated Ringer's & 5% Dextrose Injection, USP, 1000 mL
(10/12)

Hospira Issues A Voluntary Nationwide Recall Of One Lot Of Lactated Ringer's And 5% Dextrose Injection, Usp, 1000 Ml, Flexible Containers Due To Mold Contamination

Contact
Consumer:
1-877-650-7688

Media:
224-212-2357

FOR IMMEDIATE RELEASE – October 5, 2012 – Hospira, Inc. (NYSE: HSP), announced today it is initiating a voluntary user-level recall of one lot of Lactated Ringer's and 5% Dextrose Injection, USP, 1000 mL, Flexible Container, NDC 0409-7929-09. This action is due to one confirmed customer report where a leak was identified in the primary container between the cobra cap and fill-tube seal and a spore-like structured particulate, consistent with mold, was noted in the solution.

When a primary container within an overwrap has a leak, there is an open pathway for contamination of the fluid. The overwrap is not sterile, and any fluid which may have leaked out may become trapped within the overwrap and has the potential to be reintroduced into the primary container. If contaminated solution is used on a patient, critical patient harm may result. Injections of mold could potentially lead to septicemia (blood stream infections), which in a worst-case scenario may have the potential to progress to septic shock, which may be life threatening. Signs and symptoms could include injection site reactions, fever, shortness of breath, fast heart rate and feeling generally ill with nausea and vomiting.

The impacted product is identified below:

NDC #	Batch #	Expiration Date	Product Description
0409-7929-09	12-160-JT*	1DEC2013	Lactated Ringer's and 5% Dextrose Injection, USP, 1000 mL

*Note: the lot number may be followed by 01 or 90

The affected lot was distributed in all the United States with the exception of Alaska, between the dates of January 2012 and June 2012.

Hospira has not received reports of any adverse events associated with this issue for this lot, and has not identified any quality issues with retention samples for this lot. This recall is being conducted as a precautionary measure.

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

Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-877-650-7688, between the hours of 8am and 5pm EST, Monday through Friday, to arrange for the return of the product. Replacement product from other lots is available.

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.

Any adverse reactions or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administation'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.