Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: April 26, 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. Recall

SUGGESTED ACTION: **Unclassified Recall; One lot of 0.9% Sodium Chloride Injection, USP, 100 mL, Flexible Container, NDC 0409-7984-23. This action was due to one confirmed customer report where four separate particulate issues were identified in four individual flexible containers; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product was distributed in the State of Indiana. Product was distributed within the following U.S. states: Alaska, Alabama, Arizona, California, Colorado, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Michigan, Missouri, Mississippi, North Carolina, North Dakota, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, West Virginia and Wyoming. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

****

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 0.9% Sodium Chloride Injection, USP, 100 ML, Flexible Containers Due to Particulate

Contact:
Consumer
(888)597-9582

Media
(224)212-2357

FOR IMMEDIATE RELEASE - April 25, 2013 - Hospira, Inc. (NYSE: HSP), announced today that last August it initiated a voluntary nationwide user-level recall of one lot of 0.9% Sodium Chloride Injection, USP, 100 mL, Flexible Container, NDC 0409-7984-23. This action was due to one confirmed customer report where four separate particulate issues were identified in four individual flexible containers. The four single particles were identified as follows: polyester fiber, nylon fiber, cotton fiber and nitrocellulose fiber, respectively. To date, 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. A recall notification regarding this lot was previously issued to Hospira customers of record on August 31, 2012.

If solution containing particulate matter is used on a patient, this may result acutely in local inflammation, phlebitis, and/or generalized low-level allergic response to the particulate and/or embolize to other organs in the body. Chronically, following sequestration, granulomatous formation in the lungs is possible.

The product is used as a source of water and electrolytes and is packaged in a 100 mL flexible container, lot number 05-201-JT (the lot number may be followed by a -01). The affected product has an expiration date of May 1, 2013, and was distributed within the United States between May 2011 and August 2011 to wholesalers/distributors, hospitals and pharmacies.

Product was distributed within the following U.S. states: Alaska, Alabama, Arizona, California, Colorado, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Michigan, Missouri, Mississippi, North Carolina, North Dakota, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, West Virginia and Wyoming.

Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-888-597-9582 between the hours of 8am to 5pm ET, Monday through Friday, to arrange for the return of the product. Replacement product from other lots is available.

Hospira is investigating to determine the root cause.

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 has been conducted with the knowledge of the U.S. Food and Drug Administration (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].

###