Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: March 6, 2015

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: **0.9% Sodium Chloride Injection, USP**

SUMMARY: **Unclassified Recall; The recall is due to one confirmed customer report of particulate in a single unit.**

The recalled product is 0.9% Sodium Chloride Injection, USP, 250 mL VisIV™ flex container (NDC 0409-7983-25, Lot 45-110-C6, Expiry 1MAR2016)

This lot was distributed nationwide from December 2014 through January 2015.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-888-714-5079 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.**

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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 0.9% Sodium Chloride Injection, USP, 250 mL VisIV™ Container Due to Particulate Matter

Contact:
Consumer:
1-800-615-0187

Media:
224-212-2357

FOR IMMEDIATE RELEASE – March 5, 2015 – Lake Forest, Ill. – Hospira, Inc. (NYSE: HSP), announced today that it will initiate a voluntary nationwide recall of one lot of 0.9% Sodium Chloride Injection, USP, 250 mL VisIV™ flex container (NDC 0409-7983-25, Lot 45-110-C6, Expiry 1MAR2016) to the user level due to one confirmed customer report of particulate in a single unit. The foreign particle was confirmed by Hospira as human hair free-floating within the solution. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

In the unlikely event that the particulate breaks and pieces are able to pass through the intravenous catheter, injected particulate material may result in localized inflammation, phlebitis, allergic reaction, granuloma formation or microembolic effects (IV only) and/or low-level allergic response. Capillaries which may be as small as the size of a red blood cell, approximately seven microns in diameter, may become occluded. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk. However, the likelihood of these risks is low as there is no evidence indicating that IV injection of inert particles results in harm to patients when only a small amount over a limited period of time is administered.

Delay of therapy may occur due to observation of particulate at the point of care. However, this delay is likely to be of negligible clinical significance as this medication is administered by a health care provider and remediation is readily available.

This lot was distributed nationwide from December 2014 through January 2015. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Customers should notify all users in their facility. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the consumer level. Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-888-714-5079 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday. Hospira will provide allocation credits and make replacement product available for contracted customers.

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

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. Learn more at www.hospira.com.

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