Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 3, 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. [Drug]

AFFECTED PRODUCT: **Aminosyn™ II 10%, Sulfite-Free, 500mL, NDC 0409-4164-03 Lot 26-138-JT, Expiration Date: August 1, 2014.**

SUGGESTED ACTION: **Unclassified Recall; August 30, 2013 – Hospira, Inc. (NYSE: HSP), announced today it is initiating a voluntary nationwide user-level recall of one lot of Aminosyn™ II 10%, Sulfite-Free, 500mL, NDC 0409-4164-03 Lot 26-138-JT. This action is due to one confirmed customer report where an unknown foreign particle was included in the injection port and in contact with product. The foreign particle was confirmed by Hospira as human hair. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. This recall is being conducted as a precautionary measure. The root cause has not been determined and is under investigation.**

The affected lot was distributed nationwide between March 2013 and August 2013 to wholesalers/distributors, hospitals and pharmacies. Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-866-737-4701 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. If any recalled product is found, contact this office at 317-233-3213.

****

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 Aminosyn™ II 10%, Sulfite-Free, Due To Foreign Particulate Matter

Contact
Consumer:
Stericycle
1-866-737-4701

FOR IMMEDIATE RELEASE – August 30, 2013 – Hospira, Inc. (NYSE: HSP), announced today it is initiating a voluntary nationwide user-level recall of one lot of Aminosyn™ II 10%, Sulfite-Free, 500mL, NDC 0409-4164-03 Lot 26-138-JT. This action is due to one confirmed customer report where an unknown foreign particle was included in the injection port and in contact with product. The foreign particle was confirmed by Hospira as human hair. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. This recall is being conducted as a precautionary measure. The root cause has not been determined and is under investigation.

Aminosyn II is combined with dextrose, electrolytes, trace elements, vitamins and, in the case of total nutrient admixtures, fat emulsion as part of parenteral nutrition therapy. The FDA Safety Alert April 18, 1994 Hazards of Precipitation Associated with Parenteral Nutrition indicates a 0.22 micron air eliminating filter be used with non-lipid containing admixtures and a 1.2 micron air eliminating filter for lipid containing admixtures. If the particulate matter is not detected until the point of care, there may be a delay in therapy. In the event that the particulate was not observed, the particulate identified theoretically would not be able to pass through the intravenous catheter or an intravenous infusion. It is also unlikely that the particulate could block the infusion of solution into the patient.

In the unlikely event that the particulate breaks and pieces are able to pass through the intravenous catheter, injected particulate material may result in local inflammation, phlebitis, 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.

Aminosyn II 10% is an amino acid injection used as a source of nitrogen in the nutritional support of patients where oral nutrition cannot be tolerated and is packaged in a 500 mL flexible container, lot number 26-138-JT (the lot number may be followed by a 01) with an expiration date of August 1, 2014. The affected lot was distributed nationwide between March 2013 and August 2013 to wholesalers/distributors, hospitals and pharmacies.

Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-866-737-4701 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.

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] [2]
- Regular mail: use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/MedWatch/getforms.htm[3]
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration

#