Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 19, 2014

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 [Drug]

AFFECTED PRODUCT: **Hemoset Dual Channel Plum Sets**

SUMMARY: **Unclassified Recall; If the affected product is removed from the Plum infusion pump and used in a gravity infusion, there is a risk that over-delivery may occur.**

The two lots of Hemoset Dual Channel Plum Sets that are affected by this recall are: (list number 11241-03, lot numbers 28005-5H and 34100-5H).

The blood sets impacted by the recall were distributed to U.S. healthcare and veterinary facilities from May 2013 through Dec. 2013.

SUGGESTED ACTION: **For consumer inquiry only. Affected product should be returned to Stericycle, which can be contacted at 1-888-240-4282 (M-F, 8 a.m. - 5 p.m. ET). 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.**

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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 Announces Voluntary Nationwide Recall of Hemoset Blood Set

Contact:
Consumer:
(888) 240-4282

Medical Inquiries:
(800) 615-0187

Media:
(224) 212-2357

FOR IMMEDIATE RELEASE - March 18, 2014 - LAKE FOREST, Ill., - Hospira, Inc. (NYSE: HSP), announced today a nationwide recall of two lots of Hemoset Dual Channel Plum Sets (list number 11241-03, lot numbers 28005-5H and 34100-5H). Hospira identified that an incorrect set component was supplied and used during the manufacturing process of the impacted product lots. There have been no related customer reports received to date and Hospira is conducting this recall as a precautionary measure. Hospira previously distributed an Urgent Medical Device Recall notice to customers regarding this issue Feb. 25, 2014, detailing instructions on how to handle affected product.

The Hemostat Dual Channel Plum Set is designed to administer blood and blood products via the Plum™ infusion pump. If the Plum infusion pump is used with the affected product, the blood product will be delivered at its intended dosage and there is no risk of over-delivery. If the affected product is removed from the Plum infusion pump and used in a gravity infusion, there is a risk that over-delivery may occur. In a gravity delivery, the correct lower lid dispenses 15 drops per mL and the incorrect lower lid found dispenses 10 drops per mL. If a caregiver does not realize that each drop contains more volume, it is possible that over-delivery could occur. Over-delivery of blood products in the populations at greatest risk (e.g. neonates, patients with heart and/or kidney failure, and other patients with conditions associated with susceptibility to volume overload) may result in injuries that require medical intervention. These injuries are expected to fully resolve with medical intervention.

The blood sets impacted by the recall were distributed to U.S. healthcare and veterinary facilities from May 2013 through Dec. 2013. Customers should check inventory and immediately quarantine any affected product. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira has identified the non-conforming material and corrected the issue.

Affected product should be returned to Stericycle, which can be contacted at 1-888-240-4282 (M-F, 8 a.m. - 5 p.m. ET). 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.

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 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 FDA.

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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