Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: April 27, 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: **Preservative-Free Bupivacaine HCl Injection, USP, 0.5%**

SUMMARY: **Unclassified Recall; The recall is due to one confirmed customer complaint of orange and black, visible particles embedded and free floating within a single-dose glass teartop vial. The particles were identified as iron oxide. This recall is being carried out to the user level (both human and veterinary).**

The recalled product is one lot of Preservative-Free Bupivacaine HCl Injection, USP, 0.5% (5 mg/mL), 30 mL Single-dose (NDC: 0409-1162-02, Lot 38-515-DK, Expiry 1FEB2016)

The lot was distributed nationwide from July 2014 to September 2014.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-866-918-8770 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 Bupivacaine HCl Injection Due To Potential Iron Oxide Particulate In Glass Vials

Contact
Consumer:
1-888-345-4680

Media:
224-212-2357

FOR IMMEDIATE RELEASE – April 23, 2015 – Hospira, Inc., (NYSE: HSP) has announced today it is issuing a voluntary recall of one lot of Preservative-Free Bupivacaine HCl Injection, USP, 0.5% (5 mg/mL), 30 mL Single-dose (NDC: 0409-1162-02, Lot 38-515-DK, Expiry 1FEB2016) due to one confirmed customer complaint of orange and black, visible particles embedded and free floating within a single-dose glass teartop vial. The particles were identified as iron oxide. This recall is being carried out to the user level (both human and veterinary).

Risk factors associated with particulate include the potential for particulate to be injected and/or therapy may be delayed. If smaller pieces of the particulate break off and become free floating within the solution, it may be injected into the patient. Injected particulate may result in local inflammation, low-level allergic or immune responses, granuloma formation or mechanical irritation of tissue, in particular in patients allergic or sensitive to iron oxide. In addition, therapy may be delayed if observation of particulate is not made until the point of care. This delay is likely to be of negligible clinical significance provided remediation is readily available.

The lot was distributed from July 2014 to September 2014. Hospira has not received reports of any adverse events associated with this issue for this lot to date. Hospira is currently working with our glass supplier and 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 user level (both human and veterinary). Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle. For additional assistance, call Stericycle at 1-866-918-8770 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

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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