Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

**DATE:** April 18, 2012

**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 Morphine Sulfate Injection USP, 4 mg/mL (C-II), 1 mL fill in 2.5 mL Carpuject, NDC 0409-1258-30, due to a customer report of two Carpujects syringes containing more than the 1 mL labeled fill volume; Recommend notification of affected stores via phone, fax or e-mail.**

**From the information provided by FDA, the products being recalled were distributed in the State of Indiana. The affected lot was distributed in January 2012. It was initially distributed to wholesalers and a limited number of hospitals in Arizona, Colorado, Hawaii, Illinois, Indiana, Michigan, Minnesota, Ohio, Texas and Virginia. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.**

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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 a Nationwide Voluntary Recall of One Lot of Morphine Sulfate Injection, USP 4 MG/ML, (C-II) 1 ML Fill in 2.5 ML Carpuject, That May Contain More Than The Intended Fill Volume

**Contact:**
Consumer:
Hospira Medical Communications
800-615-0187

Media:
Dan Rosenberg
224-212-3366

Financial Community:
Karen King
224-212-2711
Ruth Venning
224-212-2711

**FOR IMMEDIATE RELEASE** - April 17, 2011 - Hospira, Inc. (NYSE: HSP), announced today it is initiating a voluntary user level recall of one lot of Morphine Sulfate Injection USP, 4 mg/mL (C-II), 1 mL fill in 2.5 mL Carpuject, NDC 0409-1258-30, due to a customer report of two Carpujects syringes containing more than the 1 mL labeled fill volume.

Opioid pain medications such as morphine have life-threatening consequences if overdosed. Those consequences can include respiratory depression (slowed breathing or suspension of breathing), and low blood pressure.

The affected product is a prefilled glass cartridge for use with the Carpuject™ Syringe system. The affected lot number is 10830LL. The expiration date is April 1, 2013. Morphine Sulfate Carpujects 4 mg/mL are packaged in Slim-Pak® tamper detection packages with each box containing 10 Carpujects (NDC 0409-1258-30).

The affected lot was distributed in January 2012. It was initially distributed to wholesalers and a limited number of hospitals in Arizona, Colorado, Hawaii, Illinois, Indiana, Michigan, Minnesota, Ohio, Texas and Virginia.

Hospira has not received any reports of adverse events related to this issue for this lot. This is believed to be an isolated event, and Hospira has initiated an investigation to determine the root cause and preventive actions. Consumers should contact their physician or healthcare provider if they have experianced any problems that may be related to taking or using this product.

Anyone with an existing inventory of affected product should stop use and distribution and quarantine the product immediately and call Stericycle at 1-888-912-7088 to arrange for the return of the product. Replacement product from other lots is available. Customers can send their DEA 222 form to Hospira, 1635 Stone Ridge Drive, Stone Mountain, GA 30083 to order replacement product.

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.

Any adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Events Program either online, buy regular mail or by by fax.

- **Online:** www.fda.gov/medwatch/report.htm[1]
- **Regular Mail:** use postage-paid, pre-addressed Form FDA3500 available at www.fda.gove/MedWatch/getforms.htm[2]
- **Fax:** 1-800-FDA-0178

**This recall is being 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 15,000 employees. Learn more at www.hospira.com[3] [4].

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