Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: February 18, 2016

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Pharmakon Pharmaceuticals – RECALL [Drug]

AFFECTED PRODUCT: **Morphine Sulfate 0.5 mg/mL Preservative Free in 0.9% Sodium Chloride, 1 mL Syringe, CII, for intravenous use**

SUMMARY: **Unclassified Recall; The recall has been initiated because the product is super-potent.**

The recalled product was made on February 3, 2016, with an expiration date of March 19, 2016, and labeled with lot E52418EV11C and NDC 45183-0322-78.

The recalled product was distributed to two medical facilities - one in Indiana and one in Illinois.

SUGGESTED ACTION: **For consumer inquiry only. Patients who have received this drug product and who have concerns should contact their health care professionals.**

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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.

FDA Announces Pharmakon Pharmaceuticals Voluntary Recall of Morphine Sulfate 0.5 mg/mL Preservative Free in 0.9% Sodium Chloride

For Immediate Release

February 16, 2016

Contact

Consumers

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Announcement

The U.S. Food and Drug Administration is alerting health care professionals of a voluntary recall of morphine sulfate 0.5 mg/mL preservative free in 0.9% sodium chloride, 1 mL syringe, CII, for intravenous use made and distributed by Pharmakon Pharmaceuticals, in Noblesville, Indiana, because the product is super-potent. Pharmakon initiated the voluntary recall on February 11, 2016, after receiving laboratory results showing the product was super-potent.

Injecting a patient with super-potent morphine could result in serious consequences including respiratory depression, coma, and death. Health care professionals should immediately check their medical supplies, quarantine the recalled product from Pharmakon, and not administer them to patients.

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On February 16, 2016, FDA was alerted of serious adverse events in three infants associated with the use of the recalled morphine sulfate products from Pharmakon. Patients who have received this drug product and who have concerns should contact their health care professionals.

FDA encourages health care professionals and patients to report adverse reactions to the FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

FDA inspected Pharmakon in March and April 2014, and issued a warning letter in May 2015. Pharmakon is registered under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) as an outsourcing facility. The Drug Quality and Security Act, signed into law on November 27, 2013, added a new section 503B to the FDCA. Under section 503B, a compounder can elect to become an outsourcing facility. Outsourcing facilities:

- Must comply with current good manufacturing practice requirements;
- Will be subject to inspection by FDA according to a risk-based schedule; and
- Must meet certain other requirements, such as reporting adverse events and providing FDA with certain information about the products they compound.

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