Morphine Sulfate Injection USP, 4 mg/mL (C-II), 1 mL fill in 2.5 mL Carpuject by Hospira, Inc: Recall - May Contain More Than Intended Fill Volume

[Posted 04/18/2012]

AUDIENCE: Risk Manager, Pain Management

ISSUE: 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.

BACKGROUND: The affected product is a prefilled glass cartridge for use with the Carpuject Syringe system. The affected lot number is 10830LL, with an expiration date of 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.

RECOMMENDATION: 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form 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

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