Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, April 21, 2016 1:43 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Sterile Drug Products from Pharmakon Pharmaceuticals: Recall - Lack of Sterility Assurance

UPDATED 04/20/2016. Pharmakon issues nationwide issued a voluntary nationwide recall of all sterile compounded products. All recalled products have a label that includes the Pharmakon Pharmaceuticals name, address and expiration date. The sterile products were distributed nationwide to hospitals between March 4, 2016 and April 15, 2016.

[Posted 04/16/2016]

AUDIENCE: Pharmacy, Nursing, Health Professional

ISSUE: FDA is alerting health care professionals not to use any drug products that are intended to be sterile and are produced and distributed nationwide by Pharmakon Pharmaceuticals Inc., in Noblesville, Indiana, due to a lack of sterility assurance and other quality issues.

BACKGROUND: FDA recently inspected Pharmakon's facility following the company's voluntary recall of super-potent morphine sulfate 0.5 mg/ml preservative free in 0.9% sodium chloride, 1 ml syringe, CII, for intravenous use. FDA test results showed the product to be nearly 2,500 percent the labeled potency. During the inspection, investigators observed insanitary conditions, including poor sterile production practices, and other deficiencies, which raise concerns about Pharmakon's ability to assure the sterility and quality of drug products that it produces. Additionally, FDA testing confirmed environmental contamination on multiple sites within the clean rooms, including the critical ISO-5 area.

On April 11, 2016, FDA recommended that Pharmakon cease sterile operations until appropriate corrective actions have been implemented by the facility and recall all non-expired drug products that are intended to be sterile. On April 12, 2016, Pharmakon informed FDA that it would neither initiate a recall nor cease sterile production. Therefore, FDA is alerting health care professionals not to use drug products marketed as sterile from Pharmakon.

RECOMMENDATION: Health care professionals should immediately check their medical supplies, quarantine any drug products marketed as sterile from Pharmakon, and not administer them to patients. Administration of a non-sterile drug product intended to be sterile may result in serious and potentially life-threatening infections or death.

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

[04/19/2016 - Press Release - Pharmakon Pharmaceutical, Inc.]
[04/15/2016 - CDER Alert – FDA]