From MedWatch - The FDA Safety Information and Adverse Event Reporting Program

A MedWatch Safety Alert was just added to the FDA Recalls webpage.

TOPIC: All Unexpired Sterile Drug Product Lots by Premier Pharmacy Labs: Recall - Due to Lack of Sterility Assurance

AUDIENCE: Patient, Health Professional, Pharmacy

ISSUE: The unexpired sterile drug product lots are being recalled due to concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination and lack of product specific process validations. The nationwide recall includes lots of sterile drug products to the consumer/user level.

Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening. To date, Premier Pharmacy Labs has not received any reports of adverse events related to the products. The scope of this recall is all commercially distributed product lots compounded in the Weeki Wachee, FL, location.

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.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form or submit by fax to 1-800-FDA-0178.

Read the announcement from Premier Pharmacy Labs on the FDA website.