



Clifton Health Department Food Recall Notification



Public Health
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Food/Drug/Pet Recall: Premier Pharmacy Labs

Premier Pharmacy Labs is voluntarily recalling all unexpired products, intended to be sterile, due to a lack of sterility assurance. The Unexpired Sterile Drug Product Lots (include dates dispensed) 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. The list of recalled products may be viewed at this weblink:

<https://premierpharmacylabs.com/urgent-product-recall/>

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 but is issuing this recall out of an abundance of caution following a commitment made during a recent inspection of the company's facility.

The scope of this recall is all commercially distributed product lots compounded in the Weeki Wachee, FL location currently within their labeled expiration date in response to an FDA concerns raised during the most recent inspection carried out from 29 April, 2019 to 12 June, 2019.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse reaction or quality problems experience with the use of these, or any other Premier Pharmacy Labs products, may be reported using the following options:

- . Calling Premier Pharmacy Labs at 1-800-752-7139 between the hours of 8:30 am and 5:00 pm Eastern Time.
- . Emailing to Premier Pharmacy Labs at: recalls@premierpharmacylabs.com.
- . Reporting to the FDA Medwatch Adverse Event Reporting Program at www.fda.gov/medwatch and 1-800-FDA-1088.