

Alerts and Recalls

Generic Name (Trade Name—Company)

April 12, 2018

Sterile injectable products

(No trade names—Premier Pharmacy Labs)

Recalled sterile injectable products may have microbial contamination

Uses/Notes

Premier Pharmacy Labs is voluntarily recalling [specific sterile injectable product lots](#) because they lack sterility assurance.

Microbial contamination was detected during routine testing of subsequent unreleased product lots due to interaction between the product syringe and tamper-evident container closure. This may introduce microorganisms into the products.

Administration of nonsterile injection products that are intended to be sterile may result in a site-specific or systemic infection, which in turn may cause hospitalization, significant morbidity (permanent organ damage), or a fatal outcome.

The product can be identified by the product description in the [table](#) on FDA's website and beyond-use date (BUD) on the individual product or shipping bag. The listed product lots were distributed nationwide to hospital pharmacy, clinic, and health care facilities.

To date, Premier Pharmacy Labs has not received any reports of adverse events related to this issue.

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<http://aphanet.org/alerts-and-recalls/recalled-sterile-injectable-products-may-have-microbial-contamination>

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