

From: [General Board of Pharmacy Subscriber List](#) on behalf of [Board of Pharmacy](#)
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: FDA alerts health care professionals not to use sterile drug products from Qualgen
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FDA alerts health care professionals not to use sterile drug products from Qualgen

Outsourcing facility voluntarily recalls sterile drug products, but refuses to cease sterile compounding operations

[10-10-2015] The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of lots 1 through 67 of non-expired drug products intended to be sterile produced and distributed nationwide by Qualgen LLC, in Edmond, Okla., due to lack of sterility and quality assurance. The recalled products were compounded prior to September 1, 2015.

Health care professionals should immediately check their medical supplies, quarantine any drug products marketed as sterile from Qualgen or Amerilab LLC, the facility's former name, 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.

During FDA's recent inspection of Qualgen's facility, investigators observed unsanitary conditions, including poor sterile production practices, which raise concerns about Qualgen's ability to assure the sterility of drug products that it produced.

On October 8, 2015, FDA recommended that Qualgen cease sterile operations until appropriate corrective actions have been implemented by the facility, and recall all non-expired drug products intended to be sterile. On October 9, 2015, Qualgen informed FDA that it would voluntarily recall certain lots of non-expired drug product marketed as sterile. However, the company refused to cease sterile compounding operations. Therefore, FDA alerts health care professionals and patients not to use drug products marketed as sterile from Qualgen.

To date, FDA is not aware of any adverse events associated with drug products made by Qualgen. Patients who have received any drug products produced by Qualgen and have concerns should contact their health care professional. FDA encourages health care professionals and patients to report adverse reactions or quality problems experienced with the use of these products to the [FDA's MedWatch Adverse Event Reporting](#) program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm;
or
- Download and complete the [form](#), then submit it via fax at 1-800-FDA-0178.

FDA will continue to work closely with the Oklahoma State Board of Pharmacy to protect the public health.

Qualgen is registered under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) as an [outsourcing facility](#). The Drug Quality and Security Act, signed into law on November 27, 2013, added a new section 503B to the FDCA. Under section

503B, a compounder can elect to become an outsourcing facility. Outsourcing facilities:

- Must comply with current good manufacturing practice requirements;
- Will be subject to inspection by FDA according to a risk-based schedule; and
- Must meet certain other requirements, such as reporting adverse events and providing FDA with certain information about the products they compound.

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

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