Generic Name:
Multiple generic names
Trade Name:
Multiple trade names
Company:
Pharm D Solutions
Notes:

FDA is alerting health professionals and patients not to use drug products intended to be sterile that are produced and distributed by Pharm D Solutions in Houston, TX, because they lack sterility assurance. Administration of a nonsterile drug product intended to be sterile may result in serious and potentially life-threatening infections or death.

Health professionals should immediately check their medical supplies, quarantine any purportedly sterile drug products, and not administer them to patients. They should also make alternative arrangements to obtain any medications they administer to patients from reliable sources that adhere to proper quality standards.

FDA issued a warning letter to Pharm D Solutions in December 2016 following an inspection. During FDA?s recent follow-up inspection of Pharm D?s compounding facility in August 2018, investigators observed insanitary conditions, including poor sterile production practices and deficient environmental monitoring. These conditions raised concerns about the company?s ability to ensure the sterility of its drug products.

On September 10, 2018, following FDA?s recommendation, Pharm D recalled all unexpired drug products intended to be sterile and agreed to cease sterile operations until it makes adequate corrections at its facility. However, Pharm D resumed sterile operations on October 8, 2018, and distributed purportedly sterile products without making adequate corrections at the facility. Pharm D agreed to cease sterile operations again on November 9, 2018, but has not agreed to FDA?s recommendation to recall all unexpired drug products intended to be sterile. These compounded drug products could put patients at risk.

Pharm D is registered as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act. The Drug Quality and Security Act, signed into law on Nov. 27, 2013, added a new section 503B to the FD&C Act. Under section 503B, a compounder can elect to register as an outsourcing facility.

Medication Monitor Categories:
Alerts and Recalls