

Alerts and Recalls

Generic Name (Trade Name—Company)

July 31, 2018

No trade names

(Multiple trade names—Ranier's Rx Laboratory)

Ranier's Rx Laboratory voluntary recalls all sterile compounded drug products

Uses/Notes

FDA is [alerting](#) health professionals and patients, as well as veterinarians and animal owners, of Ranier's Rx Laboratory's voluntary recall of unexpired compounded drug products intended to be sterile. The recalled products were dispensed between January 17, 2018, and July 10, 2018. See [Ranier's notification](#) for additional information.

Health professionals and veterinarians should immediately check their medical supplies, quarantine any purportedly sterile drug products, and not administer them to patients. Administration of a nonsterile drug product intended to be sterile may result in serious and potentially life-threatening infections or death.

FDA issued a [warning letter](#) to Ranier's Compounding in March 2017 following an inspection. During FDA's recent follow-up [inspection](#) of Ranier's compounding facility, investigators observed insanitary conditions, including poor sterile production practices, which raised concerns about the company's ability to ensure the sterility of its drug products.

On June 6, 2018, FDA recommended that Ranier's Compounding recall all unexpired human and animal drug products intended to be sterile and to cease sterile operations until it makes adequate corrections at its facility. On June 7, 2018, Ranier's Pharmacy informed FDA that it agreed to voluntarily recall and cease sterile operations. However, the company has failed to comply with its commitment.

To date, FDA is not aware of any adverse events associated with the use of products from Ranier's Compounding. Patients who have received drug products produced by Ranier's Compounding and have concerns should contact their health care provider.

Source URL:

<http://aphanet.org/alerts-and-recalls/ranier's-rx-laboratory-voluntary-recalls-all-sterile-compounded-drug-products>

APhA DrugInfoLine is an official publication of, and is owned and copyrighted by the American Pharmacists Association, the national professional society of pharmacists. Materials in APhA DrugInfoLine do not necessarily represent the policy, recommendations, or endorsement of APhA. The publisher, authors, editors, reviewers, and contributors have taken care to ensure that information contained in APhA DrugInfoLine is accurate and current; however, they shall have no liability to any person or entity with regard to claims, losses, or damages caused or alleged to be caused, directly or indirectly, by use of any information contained in the publication. All decisions about drug therapy must be based on the independent judgment of the clinician. Copyright © 2000–2011, American Pharmacists Association. All rights reserved.