Alerts and Recalls

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
July 31, 2018	
No trade names ***(Multiple trade names—Ranier's Rx Laboratory)*** **Ranier's Rx Laboratory voluntary recalls all sterile compounded drug products**	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.

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

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