Amikacin Sulfate Injection – Heritage Pharmaceuticals

On May 28, 2019 the U.S. Food and Drug Administration (FDA) announced that Heritage Pharmaceuticals has voluntarily recalled one lot of Amikacin Sulfate Injection. This recall is due to microbial growth having been detected in one unreleased sublot, which may indicate a lack of sterility in other sublots.

Non-sterile injectable products that are intended to be sterile may result in a site-specific or systemic infection, which in turn may cause hospitalization, organ damage or death. To date, Heritage has not received adverse event reports related to this event.

Consumers should contact their doctor for further guidance and potential change of treatment before they stop taking this drug product. Pharmacies and healthcare facilities that have the products subject to this recall should immediately stop dispensing this drug product and consumers should immediately stop using any product within these specific lots.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Consumers with questions regarding this recall should contact Qualanex at 1-800-505-9291 Monday – Friday, 8:00 am – 5:00 pm, EST and or recall@qualanex.com (mailto:recall@qualanex.com). Any adverse reactions or quality problems associated with the use of this product may be reported to ProPharma at 1-866-901-3784 at any time, and any such problems may also be reported to FDA's MedWatch Adverse Event Reporting program either by phone, online, by regular mail or by fax.