Clifton Health Department
Food Recall Notification

Public Health
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Food/Drug/Pet Recall: Heritage Pharmaceuticals, Inc.

Heritage Pharmaceuticals Inc. ("Heritage") East Brunswick, New Jersey, is initiating a voluntary recall of Amikacin Sulfate Injection, USP, 1g/4 mL (250mg/mL), Lot: VEAC025, Expiry Date: October 2019 and Prochlorperazine Edisylate Injection, USP, 10mg/2mL (5mg/mL), Lot: VPCA172, Expiry Date: April 2020, to the consumer level. These drug products are manufactured by Emcure Pharmaceuticals Ltd. ("Emcure") and distributed by Heritage. The voluntary recall is being initiated due to microbial growth having been detected in one unreleased sublot of Lot VPCA172 and one unreleased sublot Lot VEAC025, which may indicate a lack of sterility in the 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.

Amikacin Sulfate Injection is indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including Pseudomonas species, Escherichia coli, species of indole-positive and indole-negative Proteus, Providencia species, Klebsiella-Enterobacter-Serratia species, and Acinetobacter (Mima-Herellea) species.

Amikacin Sulfate Injection was manufactured in a sealed vial with a printed label affixed to the vial. Ten (10) labeled vials were packed into a carton along with a leaflet. Fifty-six (56) cartons were packed into one shipper box. Heritage began shipping Amikacin Sulfate Injection, USP, 1g/4 mL (250mg/mL), NDC # 23155-290-42, Lot: VEAC025 on June 22, 2018, and the entire lot was distributed to wholesalers and distributors in United States between June 2018, and August 2018.

Prochlorperazine Edisylate Injection is indicated to control severe nausea and vomiting and for the treatment of schizophrenia. Prochlorperazine has not been shown effective in the management of behavioral complications in patients with mental retardation.

Prochlorperazine Edisylate Injection was manufactured in a sealed vial with a printed label affixed to the vial. Five (5) labeled vials were packed into one formed PVC tray. Two (2) PVC trays were packed into a carton along with a leaflet. Twenty (20) cartons were packed into one shipper box. Heritage began shipping Prochlorperazine Edisylate Injection, USP, 10mg/2mL (5mg/mL), NDC # 2315529442, Lot: VPCA172, on October 31, 2018, which was distributed to wholesalers and distributors in United States between October 2018, and November 2018.

Qualanex is notifying Heritage consignees by recall notification and arranging for return of the recalled product.

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. 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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
. Complete and submit the report Online
. Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.