Magellan Medicaid Administration

Kilitch Healthcare India Issues Voluntary Nationwide Recall of Various Eye Drops for Potential Safety Reasons

Date: 11/15/2023

About this recall:
Kilitch Healthcare India has voluntarily recalled the eye drop products listed at the company announcement. The recall is to the consumer level for all lots within expiry (expiration dates: Nov. 2023 to Sept. 2025) for all of the listed products. These products are being recalled due to potential safety concerns after United States (US) Food and Drug Administration (FDA) investigators found insanitary conditions.

The products are available over the counter (OTC) for temporary relief of discomfort due to minor irritations of the eye or due to exposure to wind/sun and as a protectant against further irritation or to relieve dryness of the eye.

What this means to you:
For those patients who use these products, there is a potential risk of eye infections. These products are intended to be sterile. Eye drop products have an increased risk of harm as drugs applied to the eye bypass some of the body's natural defenses.

Consumers should stop using the recalled eye drops and may return any of the listed products to the place of purchase. Consumers with questions regarding this recall can contact regulatory@velocitypharma.com or regulatory@kilitchhealthcare.com. Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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 US FDA.

For more information regarding this FDA Recall Notification, please refer to the FDA website:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kilitch-healthcare-india-limited-issues-voluntary-nationwide-recall-various-eye-drops-potential
and
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kilitch-healthcare-india-limited-issues-amendments-last-voluntary-nationwide-recall-press-release (amendments press release)

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.