

The Harvard Drug Group Issues Voluntary Nationwide Recall of Certain Rugby® Brand Eye Drops Supplied by Velocity Due to Potential Risk of Eye Infections

Date: 11/01/2023

About this recall:

The Harvard Drug Group, doing business as Major® and Rugby®, is initiating a voluntary recall for **all lots** (batches) of Polyvinyl Alcohol, 1.4% Lubricating Eye Drops (NDC 00536-1325-94) and Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%; NDC 00536-1282-94) supplied by Velocity to the consumer level. The recall is due to insanitary conditions in the manufacturing facility and positive bacterial test results from sampling of drug production areas.

These products are available over the counter (OTC) for temporary relief of discomfort due to irritation of the eye or due to exposure to wind and sun. The eye drops also protect against further irritation and can relieve dryness of the eye.

What this means to you:

For those patients who use these products, there is a risk for eye infections that could result in partial vision loss or blindness. These products should be sterile. Eye drops have a higher risk as applying to the eyes bypasses some of the body's natural defenses.

Consumers should stop using the recalled eye drop products and may return any of the above listed products to the place of purchase. Consumers with questions regarding this recall can contact Sedgwick by phone at 1-866-891-1981 (8:00 am to 5:00 pm EST Monday through Friday) or by email address at harvarddrug8430@sedgwick.com. Consumers who have signs or symptoms of an eye infection after using these products should talk to their healthcare provider or seek medical care immediately.

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 United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website:
<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/harvard-drug-group-llc-issues-voluntary-nationwide-recall-certain-rugby-laboratories-brand-eye>

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.