



**URGENT: DRUG RECALL**  
**Rugby® Laboratories Branded**  
**Polyvinyl Alcohol, 1.4% Lubricating Eye Drops and**  
**Lubricating Tears Eye Drops (Dextran/Hypromellose 0.1%/0.3%)**  
**Supplied by Velocity Pharma**

October 31, 2023

The Harvard Drug Group, LLC d/b/a Major® Pharmaceuticals and Rugby® Laboratories  
 341 Mason Road  
 La Vergne, TN 37086

Dear Customer:

This letter is to inform you of a recall involving all lots of the following Rugby® Laboratories branded products supplied by Velocity Pharma:

Product Name	Package Description	Brand Name	NDC
Polyvinyl Alcohol, 1.4% Lubricating Eye Drops	0.5 oz bottle (15 mL)	Rugby®	0536-1325-94
Lubricating Tears Eye Drops (Dextran/ Hypromellose, 0.1%/0.3%)	0.5 oz bottle (15 mL)	Rugby®	0536-1282-94

Please see enclosed product labeling.

This voluntary recall has been initiated based upon information provided by FDA indicating investigators found insanitary conditions in the manufacturing facility and positive bacterial test results from environmental sampling of critical drug production areas in the facility. There is a potential risk of eye infections that could result in partial vision loss or blindness.

We began shipping this product on June 1, 2021.

Immediately examine your inventory and quarantine products subject to recall. In addition, if you may have further distributed these products, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

This recall should be carried out to the consumer level. Your assistance is appreciated and necessary to prevent patient harm.

Please complete and fax the enclosed response form as soon as possible even if you do not have the recalled products and fax to 1-888-627-2279 or email to [harvarddrug8430@sedgwick.com](mailto:harvarddrug8430@sedgwick.com). A prepaid UPS Return Service label will be provided so the affected product can be shipped to:

Sedgwick, Inc.  
Attention: Event # 8430  
2670 Executive Drive, Suite A  
Indianapolis, IN 46241

If you have any questions regarding this notification, please contact Sedgwick, Inc. at 1-866-891-1981.

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:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) 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 made with the knowledge of the Food and Drug Administration.



Electronically signed by: Aimee  
Albanese  
Reason: Author  
Date: Oct 31, 2023 16:47 EDT

Aimee Albanese  
The Harvard Drug Group  
Manager, QRA

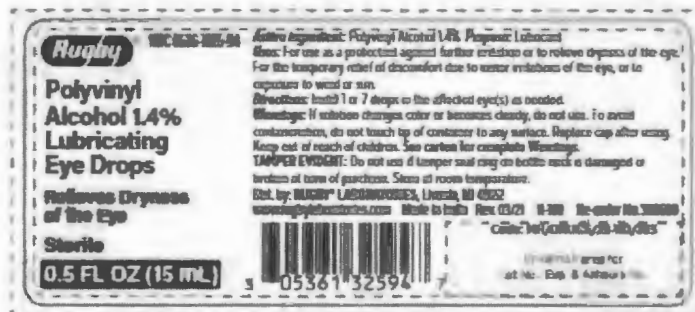
Enclosure(s)

Enclosure (s)

Example Carton Label for Polyvinyl Alcohol, 1.4% Lubricating Eye Drops, NDC 0536-1325-94



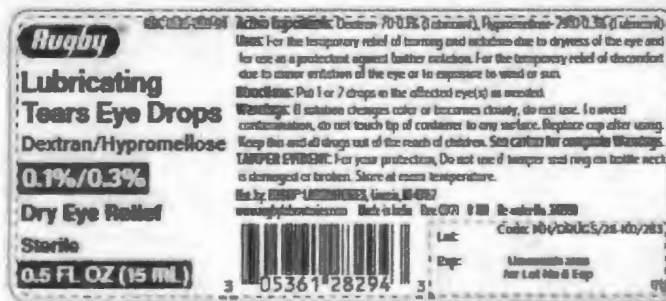
Example Bottle Label for Polyvinyl Alcohol, 1.4% Lubricating Eye Drops, NDC 0536-1325-94



Example Carton Label for Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%)



Example Bottle Label for Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%)



## URGENT: DRUG RECALL – RESPONSE FORM / PACKING SLIP

Please make a copy of this form to include with your product return shipment.

Your timely response to the recall notification is requested. Please complete form and fax to 1-888-627-2279 or email to [harvarddrug8430@sedgwick.com](mailto:harvarddrug8430@sedgwick.com).

Product Name	Package Description	Brand Name	Lot Number	NDC	# Units
Polyvinyl Alcohol, 1.4% Lubricating Eye Drops	0.5 oz bottle (15 mL)	Rugby	All Lots	0536-1325-94	
Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%)	0.5 oz bottle (15 mL)	Rugby	All Lots	0536-1282-94	

**Please check ALL appropriate boxes.**

- I have read and understand the recall instructions provided in the October 31, 2023 letter.
- We have quarantined and will return recalled product on hand.
- We do not have any of the recalled product on hand.
- I have identified and notified my customers that were shipped or may have been shipped this product by:

Date \_\_\_\_\_ Method of Notification: \_\_\_\_\_

**Any adverse events associated with recalled product?**  Yes or  No

If yes, please explain: \_\_\_\_\_

**Please check the appropriate box to describe your business:**

- |  |  |
|--|--|
| <input type="checkbox"/> Wholesaler/Distributor    | <input type="checkbox"/> Hospital Pharmacies |
| <input type="checkbox"/> Hospital/Medical Facility | <input type="checkbox"/> Repacker            |
| <input type="checkbox"/> Pharmacy – Retail         | <input type="checkbox"/> Other: _____        |

**Please complete the following information:**

Name:		Phone #:	
Wholesaler Name:		Wholesaler Account #:	
Street Address:			
City/State/Zip:			
Debit Memo #:			
Signature:		Date:	

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