URGENT: DRUG RECALL
First Aid Antiseptic Ointment (Povidone Iodine USP, 10%)

September 17, 2024

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 initiated by Zhejiang Jingwei Pharmaceutical Co., Ltd. involving:

Product Name	Package Description	Brand Name	NDC	Lot Number	Expiration Date
First Aid Antiseptic Ointment (Povidone Iodine USP, 10%)	1 oz (28.4 g)	Rugby®	0536-1271-80	220901	09/2024
				230301	03/2026
				230401	04/2026
				230501	05/2026
				230701	07/2026
				230801	08/2026
				240301	03/2027
				240501	04/2027

Please see enclosed product labeling.

This voluntary recall has been initiated by Zhejiang Jingwei Pharmaceutical Co., Ltd. due to incorrect labeling, where the inactive ingredients list Mineral Oil and Petrolatum, however, the product contains Polyethylene Glycol 400 and Polyethylene Glycol 4000. Our distribution records indicate you have received this affected product.

We began shipping this product on March 6, 2023.

Immediately examine your inventory and quarantine products subject to recall. In addition, if you may have further distributed these products, please identify your wholesale 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 wholesale 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 1-800-871-6180 or email to harvarddrug3963@sedgwick.com. A prepaid UPS Return Service label will be provided so the affected product can be shipped to:

Sedgwick, Inc.
Attention: Event # 3963
2670 Executive Drive, Suite A
Indianapolis, IN 46241

If you have any questions regarding this notification, please contact Sedgwick, Inc. at 1-877-650-8362.

This recall is being made with the knowledge of the Food and Drug Administration.

Electronically signed by: Aimee Albanese
Reason: Author
Date: Sep 17, 2024 15:26 EDT

Aimee Albanese
The Harvard Drug Group
Manager, QRA

Enclosure(s)

Enclosure (s)

Example Labeling for First Aid Ointment (Povidone Iodine USP, 10%), NDC 0536-1271-80

MAJOR Rugby™

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 1-800-871-6180 or email to harvarddrug3963@sedgwick.com.

Product Name	Package Description	Brand Name	NDC	Lot Numbers	# Cartons
First Aid Antiseptic Ointment (Povidone Iodine USP, 10%)	1 oz (28.4 g)	Rugby®	0536-1271-80	220901, 230301, 230401, 230501 230701, 230801 240301, 240501	

Please check ALL appropriate boxes.

- □ I have read and understand the recall instructions provided in the September 17, 2024 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 wholesale 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:

- □ Wholesaler/Distributor
- □ Hospital/Medical Facility
- □ Pharmacy – Retail
- □ Hospital Pharmacies
- □ Repacker
- □ 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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