

URGENT: DRUG PRODUCT RECALL

DATE March 4, 2024

Dear Customer:

This is to inform you of a voluntary product recall involving:

Digoxin Tablets, USP 125 mcg; Expiry Date: JAN 2025 (Labeled as Novitium Pharma LLC)

NDC: 70954-201-20, 1000 TABLETS in 1 BOTTLE,

Lot Number: M23172A

See the enclosed product labeling for the drug products for ease in identifying the product at the wholesale level.

This recall has been initiated due to out of specification organic impurity results for the drug product during stability testing. The out of specification results were determined to be the result of cross contamination with another drug product (mycophenolate mofetil). The product was distributed from 03/31/2023 to 06/20/2023.

Immediately examine your inventory and quarantine the subject batch. In addition, if you further distributed this product, 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.

In our best efforts to coordinate the prompt and secure return of the affected product, ANI-New Jersey (formally Novitium Pharma LLC) has contracted with Sedgwick Inc. to provide support for this recall. Instruction for the return of goods to Sedgwick is provided on the Recall Response Form (enclosed). Please complete and return the enclosed response form as soon as possible. If you have any questions, call Sedgwick at 844-388-5532 during normal business hours (8am – 5pm EST).



Sedgwick Return Management Services 2670 Executive Dr., Ste A Indianapolis, IN 46241 RE: Event #: 6084 Phone number: 844-388-5532 Fax number: 844-441-2733 Email Id: <u>ani6084@sedgwick.com</u>

ANI-New Jersey kindly requests that you provide Sedgwick Inc. with the quantities of your inventory on hand, the address and contact person at each location, as soon as possible. Enclosed you will find a form on which to record your current inventory of recalled material and the number of customers directly contacted. Please complete and return the form via fax or email (even if you have no inventory to return).

This recall is being carried out to the wholesale level. Your prompt assistance is greatly appreciated.

If you have any questions, please reach out to Sedgwick Inc. at 844-388-5532. For any medical inquiries or to report an adverse event, please contact 1-855-204-1431 Monday-Saturday (24 hours)

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

Enclosure(s)

- Recall Response Form
- Drug Product Labeling

Thanks,

George Schwab Vice President- Quality ANI Pharmaceuticals (N.J.) 70 Lake Drive East Windsor, NJ 08520

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RECALL RETURN RESPONSE FORM

Digoxin Tablets, USP 125 mcg (Labeled as Novitium Pharma LLC) M23172A; Exp Date: JAN 2025

Please check ALL appropriate boxes.

□I have read and understand the recall instructions provided in the recall letter.

□ I have checked my stock and have quarantined inventory consisting of _____ units.

Indicate disposition of recalled product:

□To Be Returned:

Quantity (# of bottles): Returned Date: Return Method:

Destroyed

Quantity (# of bottles): Method of Destruction:

□ I have identified and notified my customers that were shipped or may have been shipped this product.

□ We have NONE of the recalled lots in stock.

Any adverse events associated with recalled product?
Yes
No

If yes, please explain:

Please check the appropriate box(es) to describe your business.

- wholesaler/distributor
- □ retailer
- pharmacy retail
- hospital/medical facility
- hospital pharmacies
- medical laboratory
- Other:

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Retail Customer:	יישרידא, ואוי מאנאג לאי הפוופט ויישראל איז			
Contact Name:				
Contact Phone Number:	Contact Fax Number:			
Address:	City, State, & Zip:			
Wholesaler Name:	Wholesaler City & State:			

PLEASE E-MAIL OR MAIL COMPLETED RESPONSE FORM TO Email: ani6084@sedgwick.com

OR MAIL TO:

Sedgwick Return Management Services 2670 Executive Dr., Ste A Indianapolis, IN 46241 RE: Event #: 6084

Phone Number: 844-388-5532 Fax Number: 844-441-2733

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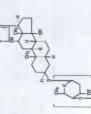
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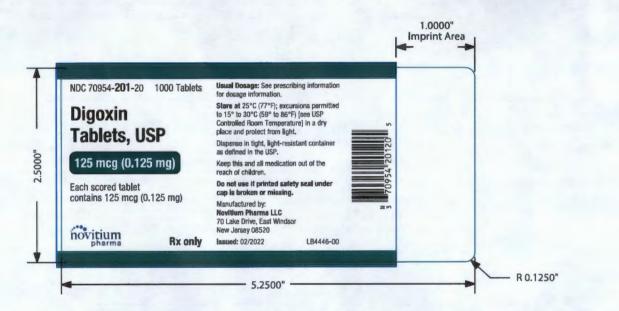
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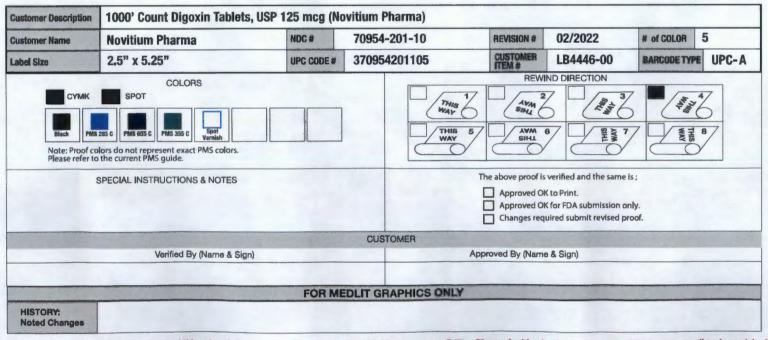
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