



Lannett Company, Inc.
13200 Townsend Road
Philadelphia, PA 19154
(215) 333-9000

UPDATE

URGENT: HYDROXYZINE HYDROCHLORIDE ORAL SOLUTION RECALL

October 22, 2018

To Whom It May Concern;

This is to inform you of a product recall involving:

Hydroxyzine Hydrochloride Oral Solution 10mg/5mL, 473mL (1 pint) Lot# 1097 Expiration: 10/2018 NDC 54838-502-80.

This recall has been initiated due to the presence of unknown impurities found during the stability testing near the expiration date of Hydroxyzine Hydrochloride Oral Solution as a potential result of previous cleaning practices that have since been improved. This recall is limited to Lot# 1097 and is being carried out to the **retail level only**.

Immediately examine your inventory and quarantine product subject to the recall. We ask that you complete the attached response form as soon as possible and return it to Lannett Customer Service via e-mail at customerservice@lannett.com. All return requests will be provided a return authorization form. Product on hand is to be returned to Lannett Company, Inc at 13200 Townsend Road, Philadelphia, PA 19154.

Additionally, if the product was further distributed, please identify the customers and notify them immediately of this product recall.

Please contact Customer Service with any questions or concerns at (215) 333-9000 ext. 4 or customerservice@lannett.com. Hours of operation are 8:00am – 4:30pm, EST.

Your assistance is appreciated. We sincerely regret this inconvenience.

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

Regards,

Andi B. Robbins
Quality Compliance Manager
Lannett Company, Inc
13200 Townsend Road
Philadelphia, PA 19154
(215) 333-9000 ext. 2263



13200 Townsend Rd.
Philadelphia, PA 19154

RECALL RETURN RESPONSE FORM

Hydroxyzine Hydrochloride Oral Solution 10mg/5mL, 473mL
Lot# 1097 Expiration: 10/2018
NDC 54838-502-80.

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the <date> letter.
- I have checked my stock and have quarantined inventory consisting of _____ <units or cases>.
- Indicate disposition of recalled product:
 - returned (**specify quantity, date and method**)/held for return;
 - destroyed (**specify quantity, date and method**);
 - quarantined pending correction (**specify quantity**);
- I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**); <or> Attached is a list of customers who received/may have received this product. Please notify my customers.

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
- grocery corporate headquarters food service/restaurant
- repacker
- manufacturer
- pharmacy - retail hospital/medical facility
- hospital pharmacies medical laboratory
- Other: _____

Name: _____

Title: _____

Tel. number: () _____

PLEASE EMAIL COMPLETED RESPONSE FORM TO:
CUSTOMERSERVICE@LANNETT.COM

OR MAIL TO: **Lannett Company, Inc.**

13200 Townsend Road

Philadelphia, PA 19154

Tel: (215) 333-9000 x 4