



RETAIL LEVEL RECALL

12/7/17

Dear Member,

Mayne Pharma is conducting a voluntary recall of one lot, as referenced above, of Liothyronine Sodium Tablets, USP, 25mcg 100 count bottles to the retail level.

The lot is being recalled due to an out of specification result obtained for dissolution testing of one tablet in a 6-tablet test at the 12-month stability time point. One vessel of 6 did not meet less than Q-25% for tablet dissolution. These lots were distributed in the US market between November 16, 2016 and January 15, 2017.

PRODUCT RECALLED BY MAYNE PHARMA

<u>MUTUAL ITEM #</u>	<u>PRODUCT</u>	<u>NDC Number</u>	<u>LOT #</u>
718-825	LIOTHYRONINE SOD 25MCG 100 CT	0574-0222-01	16F649

With this recall, you are asked to:

- Check your product for the affected Lots.
- Stop dispensing and quarantine all impacted product.
- **DO NOT RETURN PRODUCT TO MUTUAL DRUG.**
- **Complete the attached reply form and return per the instructions on the form.**
- Contact Brent Slaughter if you have additional questions.

RECALL STOCK RESPONSE FORM

LIOTHYRONINE SOD 25 MCG TABLETS VOLUNTARY RECALL 11/28/2017

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name _____ DEA # _____

**DEA # is required, if not provided the processing of your form will be delayed.*

Address _____

City _____ State _____ Zip _____

Contact Name (please print) _____ Telephone # _____

Contact Signature _____ Date _____

I have checked my stock and:

_____ Do not have any stock of the recalled **items**.

OR

I have quarantined and listed in the box below the qty of recalled units I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels _____.

Item Description	NDC	Lot #	Qty returning
LIOTHYRONINE SOD 25 MCG TABLETS	05740-222-01	16F649	

If you did not purchase the product directly from the Manufacturer please complete the below section.

Purchased From: Wholesaler Name _____ DEA # _____

City _____ State _____

If you have any questions regarding this form or product return please contact Inmar at 1-800-967-5952. Office hours 9am to 5pm Mon thru Fri.

**Please fax this form to: 1-817-868-5362 or E-mail
rxrecalls@inmar.com**