SUN PHARMA

URGENT: DRUG RECALL

Liothyronine Sodium Tablets, USP 5 mcg

December 4, 2023

Dear Customer,

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

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0059A	62756-589-88	12/2023
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0060A	62756-589-88	12/2023
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0061A	62756-589-88	12/2023
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0062A	62756-589-88	01/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0063A	62756-589-88	01/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0064A	62756-589-88	01/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0065A	62756-589-88	01/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0180A	62756-589-88	01/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0181A	62756-589-88	01/2024

Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0182A	62756-589-88	01/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0183A	62756-589-88	01/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0184A	62756-589-88	01/2024
Liothyronine Sodium Tablets, USP 5 mcg	100 tablets in 1 bottle	DND0597A	62756-589-88	02/2024

See enclosed product labeling.

This recall has been initiated in response to an Out of Specification (OOS) result reported for individual unknown impurity in Liothyronine Sodium Tablets, 5 mcg. A total of thirteen (13) batches of Liothyronine Sodium Tablets, USP 5 mcg were Out of Specification.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on March 3, 2022.

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

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-877-285-9681 Monday to Friday from 8:30 am to 5:00 pm (EST).

Please complete and return the enclosed response form as soon as possible. After receipt of the response form, a return kit will be provided so the affected product can be sent to:

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

This recall should be carried out to the retail level.

Your assistance is appreciated and necessary to prevent patient harm.

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

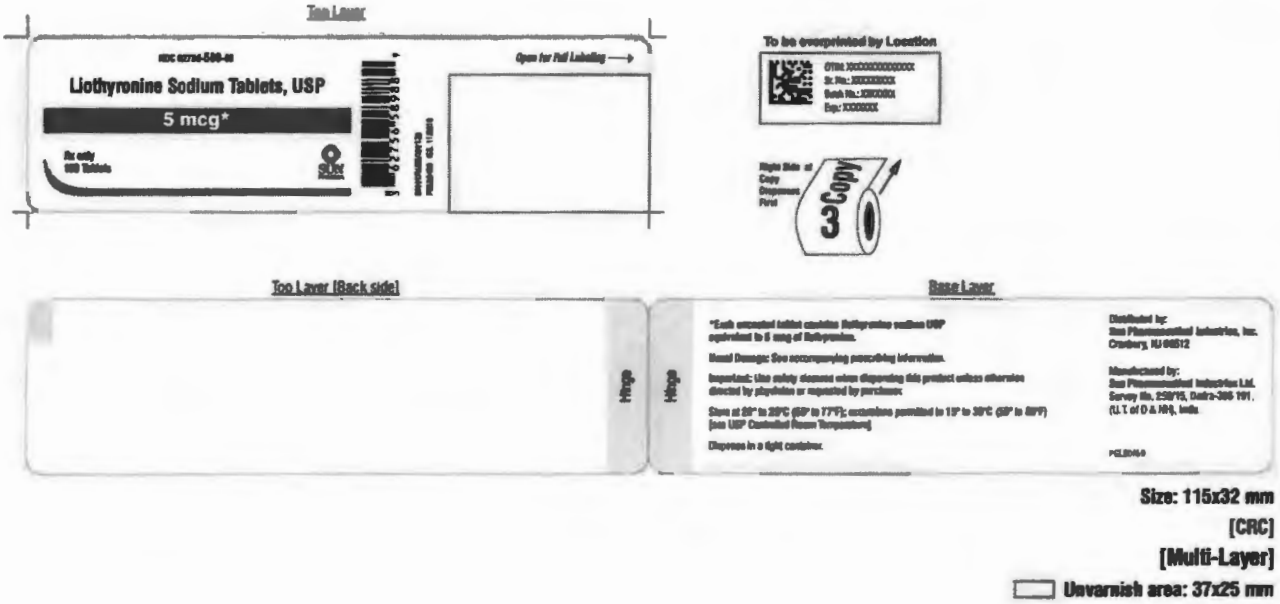
Christopher Leonor 12/04/2023

Christopher Leonor
Sun Pharmaceutical Industries, Inc.
Associate Director, North America Supply Chain Quality & FDA Liaison

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-877-285-9681.

Enclosures:

Liothyronine Sodium Tablets, USP 5 mcg: Label



For return of affected product, please email rxrecalls@inmar.com or call 1-877-285-9681.

SUN PHARMA

URGENT: DRUG RECALL – RESPONSE FORM

Please Complete This Form and Fax to: 817-868-5362
or Email to: rxrecalls@inmar.com

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the December 4, 2023 letter.

□ I have checked our stock and have quarantined inventory consisting of _____ units (number of full cartons) or _____ prescription packs (partial cartons).

□ Indicate disposition of recalled product:

□ returned **(specify quantity, date and method)**/held for return;

Number of Labels Required for Return to Inmar: _____

□ previously destroyed **(specify quantity, date and method)**;

□ I have identified and notified my retail customers that were shipped or may have been shipped this product by **(specify date and method of notification)**; or

□ Attached is a list of retail 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: _____

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

- □ wholesaler/distributor
- □ grocery corporate headquarters
- □ repacker
- □ pharmacy
- □ retailer
- □ hospital pharmacies
- □ hospital/medical facility
- □ Other:

Customer Name: _____ Title: _____

Company: _____ DEA Number: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____

Customer Debit Memo Number: _____

Wholesaler: _____ City\State: _____

Wholesaler DEA Number: _____

Event ID RCL234-23 / N130994

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