

URGENT: DRUG RECALL

Levothyroxine Sodium Tablets, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 112 mcg, 125 mcg, and 150 mcg

July 10, 2026

Dear Customer:

This letter is to inform of a product recall involving:

Product Name	Package Description	Brand Name	NDC	Lot Number	Expiration Date
Levothyroxine Sodium Tablets, USP, 25 mcg	100 Unit Doses (10 x 10 blister packs)	Major®	0904-6949-61	N02212	07/2026
Levothyroxine Sodium Tablets, USP, 50 mcg	100 Unit Doses (10 x 10 blister packs)	Major®	0904-6950-61	N02200	10/2026
Levothyroxine Sodium Tablets, USP, 75 mcg	100 Unit Doses (10 x 10 blister packs)	Major®	0904-6951-61	N02172	07/2026
				N02296	12/2026
				N02288	12/2026
Levothyroxine Sodium Tablets, USP, 88 mcg	100 Unit Doses (10 x 10 blister packs)	Major®	0904-6952-61	N02310	01/2027
Levothyroxine Sodium Tablets, USP, 112 mcg	100 Unit Doses (10 x 10 blister packs)	Major®	0904-6954-61	N02203	09/2026
Levothyroxine Sodium Tablets, USP, 125 mcg	100 Unit Doses (10 x 10 blister packs)	Major®	0904-6955-61	N02266	11/2026
Levothyroxine Sodium Tablets, USP, 150 mcg	100 Unit Doses (10 x 10 blister packs)	Major®	0904-6956-61	N02167	07/2026
Levothyroxine Sodium Tablets, USP, 25 mcg	10 Unit Doses (10 x 1 blister packs)	Cardinal	Bag: 55154-3558-0 Blister: 0904-6949-61	Bag: N02212A Blister: N02212	07/2026
				Bag: N02212B Blister: N02212	07/2026
Levothyroxine Sodium Tablets, USP, 50 mcg	10 Unit Doses (10 x 1 blister packs)	Cardinal	Bag: 55154-3559-0 Blister: 0904-6950-61	Bag: N02200A Blister: N02200	10/2026
				Bag: N02200B Blister: N02200	10/2026

Product Name	Package Description	Brand Name	NDC	Lot Number	Expiration Date
Levothyroxine Sodium Tablets, USP, 75 mcg	10 Unit Doses (10 x 1 blister packs)	Cardinal	Bag: 55154-3560-0 Blister: 0904-6951-61	Bag: N02172A Blister: N02172	07/2026
				Bag: N02172B Blister: N02172	07/2026
				Bag: N02288A Blister: N02288	12/2026
				Bag: N02288B Blister: N02288	12/2026
Levothyroxine Sodium Tablets, USP, 125 mcg	10 Unit Doses (10 x 1 blister packs)	Cardinal	Bag: 55154-3562-0 Blister: 0904-6955-61	Bag: N02266A Blister: N02266	11/2026
				Bag: N02266B Blister: N02266	11/2026
Levothyroxine Sodium Tablets, USP, 150 mcg	10 Unit Doses (10 x 1 blister packs)	Cardinal	Bag: 55154-3563-0 Blister: 0904-6956-61	Bag: N02167A Blister: N02167	07/2026

Please see enclosed product labeling.

This voluntary recall has been initiated due to out of specification results obtained during routine stability testing for Assay. Use of this product is not likely to cause adverse health effects.

We began shipping this product on January 22, 2025.

Immediately examine your inventory and quarantine products subject to recall. In addition, if you may have further distributed these products, please identify your wholesale and retail customers and notify them at once of this product recall. Please direct your customers to return the product subject to recall to the place of purchase. 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 retail 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 1-800-507-7642 or email to harvarddrug8147@sedgwick.com. We request you complete and return the enclosed response form within 14 days, and that all identified product be returned no later than 45 days from the date of this letter. A prepaid UPS Return Service label will be provided so the affected product can be shipped to:

Sedgwick, Inc.
Attention: Event # 8147
2670 Executive Drive, Suite A
Indianapolis, IN 46241

If you have any questions regarding this notification, please contact Sedgwick, Inc. at 1-800-386-4756 (8:00 am – 5:00 pm EST Monday through Friday).

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

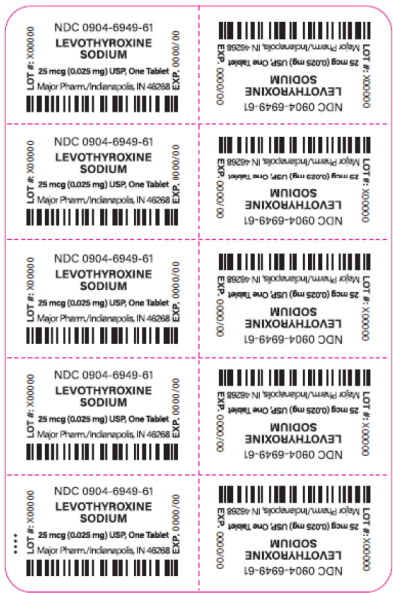
A handwritten signature in black ink, appearing to read "Aimee Albanese".
Electronically signed by: Aimee Albanese
Reason: Author
Date: Jul 10, 2026 07:20:17 EDT

Aimee Albanese
The Harvard Drug Group, LLC d/b/a Major® Pharmaceuticals and Rugby® Laboratories
Manager, QRA

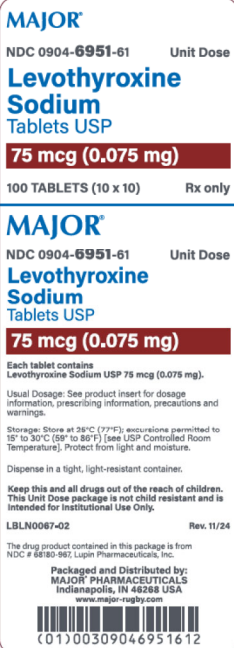
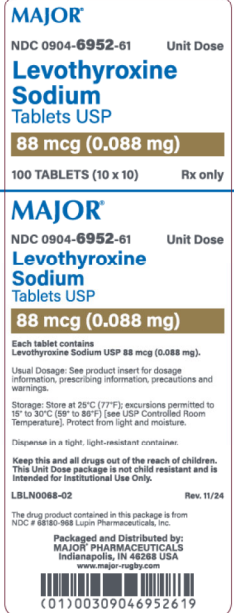
Enclosure(s)

Enclosure (s)

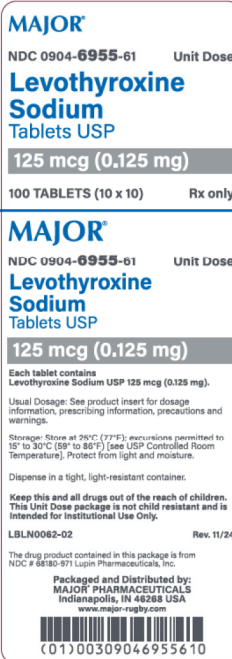
Example Labeling for Levothyroxine Sodium Tablets

Strength	NDC	Blister Labeling	Saleable Unit Labeling
25 mcg	0904-6949-61		
50 mcg	0904-6950-61		

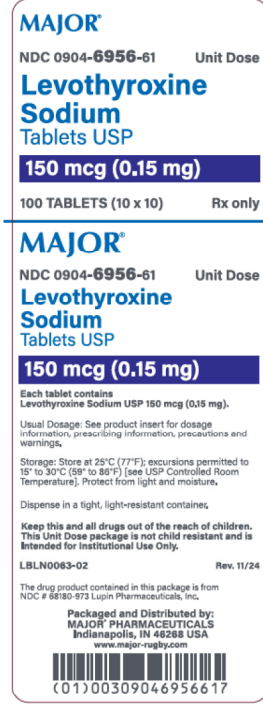
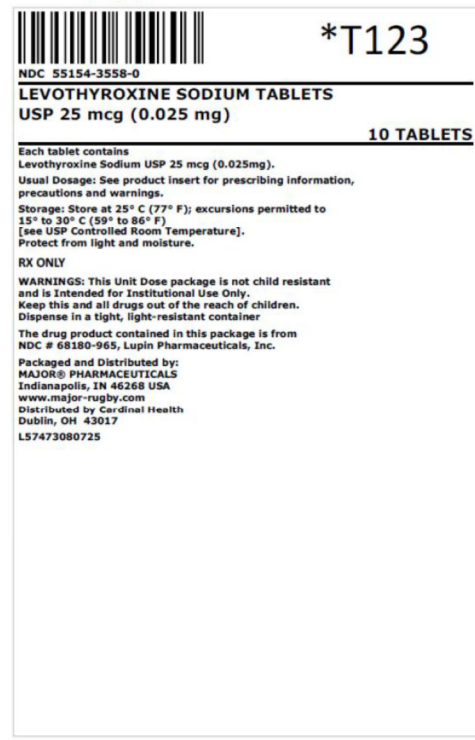
Example Labeling for Levothyroxine Sodium Tablets, continued

Strength	NDC	Blister Labeling	Saleable Unit Labeling
75 mcg	0904-6951-61		
88 mcg	0904-6952-61		

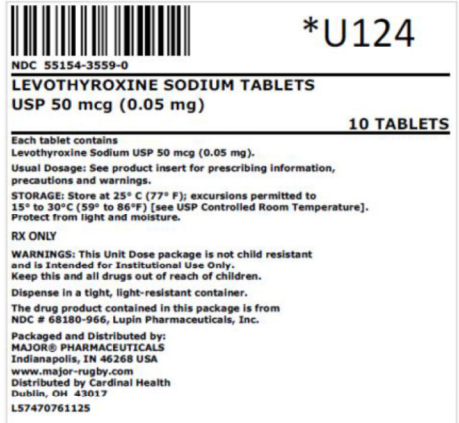
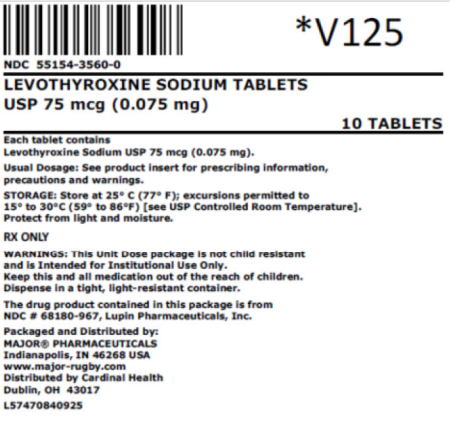
Example Labeling for Levothyroxine Sodium Tablets, continued

Strength	NDC	Blister Labeling	Saleable Unit Labeling
112 mcg	0904-6954-61		
125 mcg	0904-6955-61		

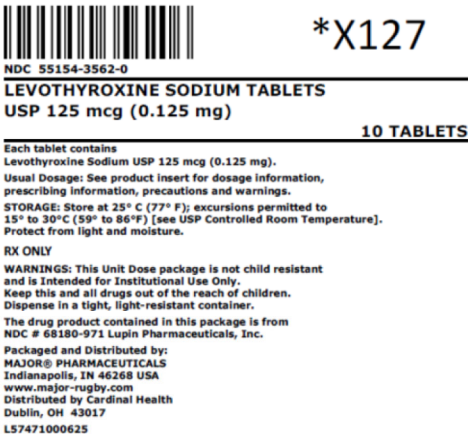
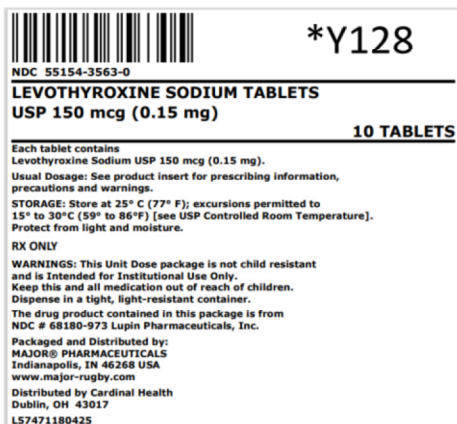
Example Labeling for Levothyroxine Sodium Tablets, continued

Strength	NDC	Blister Labeling	Saleable Unit Labeling
150 mcg	0904-6956-61		
25 mcg	Bag: 55154-3558-0 Blister: 0904-6949-61		

Example Labeling for Levothyroxine Sodium Tablets, continued

Strength	NDC	Blister Labeling	Saleable Unit Labeling
50 mcg	Bag: 55154-3559-0 Blister: 0904-6950-61		
75 mcg	Bag: 55154-3560-0 Blister: 0904-6951-61		

Example Labeling for Levothyroxine Sodium Tablets, continued

Strength	NDC	Blister Labeling	Saleable Unit Labeling
125 mcg	Bag: 55154-3562-0 Blister: 0904-6951-61		
150 mcg	Bag: 55154-3562-0 Blister: 0904-6951-61		

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 1-800-507-7642 or email to harvarddrug8147@sedgwick.com.

Levothyroxine Sodium Tablets, USP Strength	Package Description	Brand Name	NDC	Lot Numbers	# of Tablets
25 mcg	100 Unit Doses (10 x 10 blister packs)	Major®	0904-6949-61	N02212	
50 mcg			0904-6950-61	N02200	
75 mcg			0904-6951-61	N02172, N02296, and N02288	
88 mcg			0904-6952-61	N02310	
112 mcg			0904-6954-61	N02203	
125 mcg			0904-6955-61	N02266	
150 mcg			0904-6956-61	N02167	
25 mcg	10 Unit Doses (10 x 1 blister packs)	Cardinal	Bag: 55154-3558-0 Blister: 0904-6949-61	N02212A and N02212B (Bag)	
				N02212 (Blister)	
50 mcg			Bag: 55154-3559-0 Blister: 0904-6950-61	N02200A and N02200B (Bag)	
				N02200 (Blister)	
75 mcg			Bag: 55154-3560-0 Blister: 0904-6951-61	N02172A, N02172B, N02288A, and N02288B (Bag)	
				N02172 and N02288 (Blister)	
125 mcg			Bag: 55154-3562-0 Blister: 0904-6955-61	N02266A and N02266B (Bag)	
				N02266 (Blister)	
150 mcg			Bag: 55154-3563-0 Blister: 0904-6956-61	N02167A (Bag)	
				N02167 (Blister)	

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Please check ALL appropriate boxes.

- ☐ I have read and understand the recall instructions provided in the July 10, 2026 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 and retail 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 Pharmacies |
| ☐ Hospital/Medical Facility | ☐ Repacker |
| ☐ Pharmacy – Retail | ☐ Other: _____ |

Please complete the following information:

Name:		
Place of Business Name:		
Street Address, City, State, Zip:		
Phone or Email:		
Wholesaler Name:		Wholesaler Account #:
Debit Memo #:		
Signature/Date:		