



April 22, 2014

URGENT DRUG RECALL

Liothyronine Sodium Tablets, USP 5 mcg

Dear valued customer:

The purpose of this letter is to inform you that Sigmapharm Laboratories, LLC (“Sigmapharm”) is initiating a Voluntary Recall of its Liothyronine Sodium Tablets, USP 5 mcg, for the lot numbers listed below. This recall is being conducted due to the finding of a potential carryover of trace amounts of a previously manufactured product in these four lots of Liothyronine Sodium Tablets, USP 5 mcg. Based on a medical assessment performed, adverse health consequences are unlikely to occur due to this issue.

This Voluntary Recall is being conducted at a **Retail Level** with the knowledge of the Food and Drug Administration. All locations that received direct shipments of these lots from Sigmapharm are being notified of this recall.

Product	NDC Number	Lot Numbers	Exp Date	Manufacturer and Distributor
Liothyronine Sodium Tablets, USP 5 mcg	42794-018-02	1302201	JAN 2015	Sigmapharm Laboratories, LLC
	42794-018-06	1302202	JAN 2015	
	42794-018-02	1305501	MAR 2015	
	42794-018-02	1314801	OCT 2015	

Our records indicate that you have been receiving shipments of these lots since March 2013. Therefore, please examine your inventory immediately to determine if you have any quantities of these lots.

We ask for your cooperation in taking the following actions:

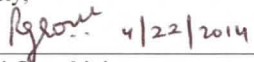
1. Immediately stop distribution of these lots only and quarantine any quantities of these lots remaining in your control.
2. If you have further distributed these lots, up to and including the Retail Level, please contact these accounts immediately, advise them of the recall and have them return their outstanding recalled stock to you for return. Please advise your accounts that this recall is to the Retail Level and to complete the Recall Response Form, noted below.
3. Conduct a physical count and record this data on the Recall Return Response Form.
4. Mail, Fax or Email the completed Recall Return Response Form even if you do not have the recalled product in your inventory.
5. Mail to: DLSS Regulatory, 4580 S. Mendenhall Road, Memphis, TN 38141
 - a. Fax to: 1-901-368-6903.
 - b. Email to: DDNRegulatory@ddnnet.com
6. Return product to:
Dohmen Life Science Services (DLSS), LLC
ATTN: Returns Department
4580 S. Mendenhall Road
Memphis, TN 38141

NOTE: A call tag, a pre-printed, pre-paid return label will be provided to you for product return; return shipment is free of charge. For the call tag, contact Customer Service at 1-855-206-7815, option 1. You will be asked for the number of boxes/product being returned and contact information which are required for generation of the call tag.

For questions related to the return of these products, contact Customer Service at 1-855-206-7815, option 1 on Monday through Friday between 9AM – 5PM CDT. If you have any other questions related to this recall, please contact Sigmapharm’s Sales & Marketing Department: Mr. Kee Moore (at 215-352-6655, Ext 258) or Ms. Grace Wilks (at 215-352-6655, Ext 241).

We appreciate your immediate attention and cooperation and apologize for any inconvenience caused by this action.

Sincerely,


FOY **Dr. Lai Ogunbiyi**
Senior Vice President, Quality Assurance
Sigmapharm Laboratories, LLC