Lou Dallago
Vice President – US Trade Group

Pfizer Inc
235 East 42nd Street, New York, NY 10017

URGENT: DRUG RECALL

December 7, 2018

Levoxyl® (levothyroxine sodium tablets, USP)

tablets

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
60793-855-01	18A18	01/2020	112mcg	100 tablets / bottle

Dear Customer:

Pfizer Inc is voluntarily recalling the above referenced lot of **Levoxyl® (levothyroxine sodium tablets, USP) tablets** as the assay result at the six month stability time point was out of specification (above specification). Pfizer completed a Health Hazard Assessment which concluded that the use of the impacted product has a low probability of being associated with adverse events and the potential risk to patients arising from this issue is considered to be low.

FEDERAL REGULATION 21 CFR 7.49 (d) RESPONSIBILITY OF RECIPIENT STATES: "CONSIGNEES THAT RECEIVE A RECALL COMMUNICATION SHOULD IMMEDIATELY CARRY OUT THE INSTRUCTIONS SET FORTH BY THE RECALLING FIRM ..." PFIZER INC RECOMMENDS THAT YOU RESPOND TO THIS RECALL, EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED POSTAGE-PAID, BUSINESS REPLY CARD (BRC) AND RETURN IT TO US, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Stericycle Inc. at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above-referenced lot of **Levoxyl® (levothyroxine sodium tablets, USP) tablets** is being conducted to the **retail level**.

Our records indicate that you may have received shipment of the affected lot between July 2018 and September 2018. Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution immediately and promptly return it to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 5493 using the enclosed pre-paid UPS label. If you received this notification without the prepaid UPS label and BRC, require additional shipping labels, or have questions regarding the return procedure, please contact Stericycle Inc. at 1-800-805-3093.

If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they immediately cease

distribution of the affected product and promptly contact Stericycle at 1-800-805-3093 to obtain a BRC to initiate the return process.

Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 1-800-533-4535 (Mon.-Fri. 8:00am - 5:30pm ET).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you. If you have any medical questions regarding the product, please contact Pfizer Medical Information at 1-800-438-1985 (Mon.-Fri. 8am - 7pm ET).

Sincerely,

Lou Dallago
Vice President U.S. Trade Group