TARO PHARMACEUTICALS U.S.A., INC

Contact name or Department
Firm's name
Address
City, State, Zip Code

February 26, 2020

URGENT: FOLLOW-UP TO DRUG RECALL

Phenytoin Oral Suspension USP, 125 mg/5 mL

Lot #	Exp. Date	Size	NDC #	Dates Distributed
327874	Dec 2020	237 mL	**51672-4069-1**	May 3 to July 5, 2019
327876	Dec 2020	237 mL	**51672-4069-1**	July 1 to August 21, 2019

Dear Valued Customer,

On February 7, 2020, you were notified that Taro Pharmaceuticals U.S.A., Inc. voluntarily recalled to the wholesale level the two (2) lots listed above of Phenytoin Oral Suspension USP, 125 mg/5 mL, 237 mL bottles. You were requested to remove these lots from your warehouse stock.

This follow-up letter is to notify you that the Food and Drug Administration has reviewed our recall strategy and recommended that the recall be extended to the **Consumer Level**. We request that you contact your direct customers and instruct that they examine their stock to determine if they have any of the affected lots on hand. If they do, please request that they discontinue sales of these lots and promptly return all units to you or to our distribution center. Please forward all returned units to our recall center at:

Inmar Rx Solutions
3845 Grand Lakes Way
Suite 125
Grand Prairie, TX 75050
Attn: RETURNED GOODS- RECALL- Phenytoin Oral Suspension

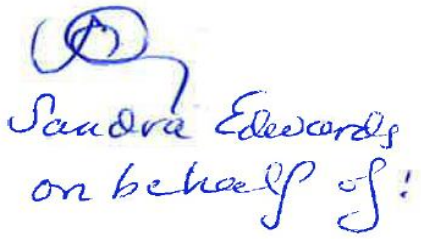
We will credit all returned merchandise to your account.

In addition, please return the attached response form as soon as possible, providing the requested information.

3 Skyline Drive, Hawthorne, NY 10532 Tel: 914-345-9001 1-888-TARO-USA Fax: 914-345-8728 www.taro.com

Taro apologizes for any inconvenience this occurrence has caused our valued customers. We appreciate your prompt attention to this matter. If you have any questions about the content of this letter or this recall, please contact our call center at 1-855-536-6300.

Sincerely,



Scott Keenan
Manager, Quality Compliance

3 Skyline Drive, Hawthorne, NY 10532 Tel: 914-345-9001 1-888-TARO-USA Fax: 914-345-8728 www.taro.com

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RECALL RESPONSE FORM – Retail Level

Phenytoin Oral Suspension USP, 125 mg/5 mL

Lot #	Exp. Date	Size	NDC	Dates Distributed
327874	Dec 2020	237 mL	**51672-4069-1**	May 3 to July 5, 2019
327876	Dec 2020	237 mL	**51672-4069-1**	July 1 to Aug 21, 2019

Please enter the following information, completely:

Wholesale Supplier/Distributor **DEA#** _____

Name: _____ Phone: _____

Address/Location: _____

Wholesaler/Distributor Account Number: _____

Retail Supplier/Distributor

Name: _____ Phone: _____

Address/Location: _____

Please check ALL that apply:

☐ I have read and understood the instructions provided in the recall letter
☐ I have checked my inventory for any stock of lot # 327874 and 327876
☐ **Check here IF YOU DO NOT have any inventory**, and please return this form
☐ Check here if you **DO** have inventory from lot #327874 and 327876 and enter the quantity to be returned below:

Lot #	Exp. Date	Quantity
327874	**Dec 2020**	
327876	**Dec 2020**	

Please FAX a copy of the completed response form to 1-817-868-5362 or return a copy of this form BY MAIL to:
Inmar Rx Solutions
3845 Grand Lakes Way
Suite 125
Grand Prairie, TX 75050
Attn: RETURNED GOODS- RECALL- Phenytoin Oral Suspension

Please include a copy of this form with your return shipment, with the Return Authorization Number entered: **Return Authorization Number:** _____

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