



Taro Pharmaceuticals U.S.A., Inc.

RECALL COORDINATOR
Drogueria Betances, Inc
AVE. LUIS MUNON MARIN
Caguas, PR 00725

February 17, 2021

FOLLOW-UP NOTIFICATION: DRUG RECALL
Nortriptyline HCl Capsules USP, 10 mg

Lot #	Exp. Date	Bottle Size	NDC	Labeler	Dates Distributed
AC05096	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/07/2020 to 12/08/2020
AC05098	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/07/2020 to 12/09/2020
AC05099	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/09/2020 to 12/14/2020

Dear Valued Customer,

On January 8, you were issued notification that Taro Pharmaceuticals U.S.A., Inc. initiated a Voluntary Recall for three (3) lots of Nortriptyline HCl Capsules USP, 10 mg, 100 count bottles (NDC 51672-4001-1) listed in the table above, which were manufactured by Taro Pharmaceuticals for distribution under the Taro label.

This follow-up letter is to notify you that the Food and Drug Administration reviewed our recall strategy and recommended that this recall should be **extended to the RETAIL LEVEL**. We request that you provide notification to any intermediate distributors and retail customers to whom you may have distributed lots AC05096, AC05098 and AC05099, and instruct them to examine their stock **immediately** to determine if they have any units from these 3 lots on hand.

If they do, **please request that they discontinue sales of Nortriptyline HCl Capsules USP, 10 mg, 100 count bottles, Lots AC05096, AC05098 and AC05099** and instruct them to promptly return all units to you or to our distribution center. All returned units of Lots AC05096, AC05098 and AC05099 should be forwarded to the Taro distribution center at:

Taro Pharmaceuticals U.S.A., Inc.
1 Commerce Drive, Cranbury, New Jersey 08512
Attn: RETURNED GOODS - RECALL - Nortriptyline HCl 10 mg Capsules

For your convenience, we have attached a Retail Customer Notification Letter and Retail Customer Response Form that you may distribute to your customers, with instructions for replying to Taro and returning any recalled merchandise.

Please also complete and return the attached Wholesaler Response Form to confirm your receipt of this notification, and to indicate if you have any units from lots AC05096, AC05098 and AC05099 to return to Taro. We will credit all returned merchandise to your account.

Please return the enclosed Wholesaler Response Form to:

Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Attention: Richard Lewellyn

or via fax: 914-470-4946
or by e-mail to: taro.returns@taro.com



Taro Pharmaceuticals U.S.A., Inc.

As you were previously informed, Nortriptyline HCl Capsules USP, 10 mg, 100 count bottles, Lots AC05096, AC05098 and AC05099 are being recalled because the quantity of active ingredient used for these product lots was inadvertently taken from an ingredient lot from an alternate supplier before that specific lot was formally qualified for use by the manufacturing site. Please be assured that this raw material lot was fully tested prior to its use and complied with all the established ingredient specifications. There are no health or safety risks associated with the continued use of Lots AC05096, AC05098 and AC05099, as both the active raw material and the product lots were fully tested and released after passing all quality specifications. Taro is recalling Lots AC05096, AC05098 and AC05099 as a precautionary measure and to remain compliant with current GMP practices. This recall is being conducted with the knowledge of the Food and Drug Administration.

Taro apologizes for any inconvenience this has caused, and we appreciate your prompt attention to this matter, and for your assistance in providing notification to your retail customers. If you have any questions about the content of this letter, please contact Richard Lewellyn at 1 800-544-1449 ext. 6334 or via email to richard.lewellyn@taro.com, or me at 914-345-9001 ext. 6216.

Sincerely,

A handwritten signature in cursive script that reads "Scott P. Keenan".

Scott Keenan
Manager, Quality Compliance

Enclosure:

- Wholesaler Response Form for Drug Recall – Nortriptyline HCl Capsules USP, 10 mg
- Retail Customer Notification Letter - Nortriptyline HCl Capsules USP, 10 mg (with Retailer Response Form)

Addressee:

Drogueria Betances, Inc



Taro Pharmaceuticals U.S.A., Inc

February 17, 2021

WHOLESALE RESPONSE FORM for DRUG RECALL

Nortriptyline HCl Capsules USP, 10 mg

Lot #	Exp. Date	Bottle Size	NDC	Labeler	Dates Distributed
AC05096	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/07/2020 to 12/08/2020
AC05098	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/07/2020 to 12/09/2020
AC05099	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/09/2020 to 12/14/2020

You are listed as a consignee for products being recalled by Taro Pharmaceuticals U.S.A. Please provide the information requested below and return this form to Taro whether or not you have any inventory of the product lots listed in the table above.

Name of Wholesaler/Distributor: _____

Location / Address: _____

Check all that apply:

- I have read and understood the instructions provided in the notification letter
- I have checked my inventory for any stock of the product lots listed in the table above
- Check here IF YOU DO NOT have any inventory, and please return this form**
- Check here if you have inventory of the impacted product lots listed in the table above

If you have inventory of the impacted lots, please enter the quantities in the table below:

Lot #	Quantity
AC05096	
AC05098	
AC05099	

Return Authorization: _____

Please E-Mail the completed response form to: taro.returns@taro.com

...or FAX the completed response form to Richard Lewellyn at: 914-470-4946

...or return the form BY MAIL to: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, New York 10532
Attention: Richard Lewellyn

(Note: Please include a copy of this form with your return shipment and provide the Return Authorization Number)



Taro Pharmaceuticals U.S.A., Inc.

February 17, 2021

DRUG RECALL
RETAIL CUSTOMER NOTIFICATION
Nortriptyline HCl Capsules USP, 10 mg

Lot #	Exp. Date	Bottle Size	NDC	Labeler	Dates Distributed
AC05096	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/07/2020 to 12/08/2020
AC05098	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/07/2020 to 12/09/2020
AC05099	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/09/2020 to 12/14/2020

Dear Valued Customer,

This is to notify you that Taro Pharmaceuticals U.S.A., Inc. is conducting a Voluntary Recall for three (3) lots of Nortriptyline HCl Capsules USP, 10 mg, 100 count bottles, Lots AC05096, AC05098 and AC05099, manufactured by Taro Pharmaceuticals for distribution under the Taro label, within the US market. Lots AC05096, AC05098 and AC05099 are being recalled because the quantity of active ingredient used for these product lots was inadvertently taken from an ingredient lot from an alternate supplier before that specific lot was formally qualified for use by the manufacturing site. Please be assured that this raw material lot was fully tested prior to its use and complied with all the established raw material specifications. There is no safety risk associated with the continued use of Lots AC05096, AC05098 and AC05099, as both the active raw material and the finished products were fully tested and released after passing all quality specifications. Taro is recalling Lots AC05096, AC05098 and AC05099 as a precautionary measure and to remain compliant with GMP practices. This recall is being conducted with the knowledge of the Food and Drug Administration.

The recall is being conducted to the **RETAIL LEVEL**. You are requested to examine your stock **immediately** to determine if you have any units of **Nortriptyline HCl Capsules USP, 10 mg, 100 count bottles, Lots AC05096, AC05098 and AC05099** on hand. If you do, please discontinue sales of these lots, and promptly return all units to the Taro distribution center at the following address:

Taro Pharmaceuticals U.S.A., Inc.
1 Commerce Drive, Cranbury, New Jersey 08512
Attn: RETURNED GOODS - RECALL - Nortriptyline HCl 10 mg Capsules

Please fill out and return the attached Retail Customer Recall Response Form with your name and address, and the name and account number of your wholesale supplier/distributor. Credit for all returned merchandise will be issued to your wholesale supplier/distributor, reflecting your account number.

Please return the enclosed Retail Customer Recall Response Form to:

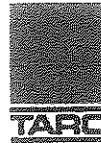
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Attention: Richard Lewellyn

or via fax: 914-470-4946
or by e-mail to: taro.returns@taro.com

Taro apologizes for any inconvenience this has caused, and we appreciate your prompt attention to this matter. If you have any questions about the content of this letter, please contact Richard Lewellyn at 1 800-544-1449 ext. 6334 or via email to richard.lewellyn@taro.com, or me at 914-345-9001 ext. 6216.

Sincerely,

Scott Keenan
Manager, Quality Compliance



Taro Pharmaceuticals U.S.A., Inc

February 17, 2021

DRUG RECALL

RETAIL CUSTOMER RECALL RESPONSE FORM

Nortriptyline HCl Capsules USP, 10 mg

Lot #	Exp. Date	Bottle Size	NDC	Labeler	Dates Distributed
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AC05099	Oct. 2022	100 count	51672-4001-1	Taro Pharmaceuticals	12/09/2020 to 12/14/2020

You are listed as a consignee or retailer for products being recalled by Taro Pharmaceuticals U.S.A. Please provide the information below and return this form to Taro whether or not you have any inventory of the above product lots.

Please provide the following information and check ALL appropriate boxes:

Name of Pharmacy/Retailer: _____ Wholesaler Account Number: _____

Address: _____

Wholesaler/Distributor Name: _____

Address: _____

Check all that apply:

- I have read and understood the instructions provided in the recall notification letter
- I have checked my inventory for any stock of the product lots listed in the table above
- Check here IF YOU DO NOT have any inventory, and please return this form
- Check here if you have inventory of the impacted product lots listed in the table above

If you have inventory of the impacted lots, please enter the quantities in the table below:

Lot #	Quantity
AC05096	
AC05098	
AC05099	

Return Authorization: _____

Please E-Mail the completed response form to: taro.returns@taro.com

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