Acella
PHARMACEUTICALS, LLC

URGENT DRUG RECALL

05/28/2020

Product	NDC	Lot #	Exp. Date
NP Thyroid® 30 mg	42192-329-01	M329A19-1	20-Dec
		M329H18-1	20-Jul
		M329J18-1	20-Aug
		M329J18-2	20-Aug
		M329J18-3	20-Aug
		M329M18-2	20-Nov
NP Thyroid® 60 mg	42192-330-01	M330J18-2A	20-Aug
		M330J18-3	20-Aug
NP Thyroid® 90 mg	42192-331-01	M331G18-1	20-Jun
		M331J18-1	20-Aug
		M331J18-2	20-Aug
		M331M18-1	20-Nov
		M331M18-2	20-Nov

Dear Customer,

Acella Pharmaceuticals, LLC is initiating a voluntary consumer level recall on 13 lots of 30 mg, 60 mg, and 90mg NP Thyroid®. This recall is being conducted with the knowledge of the Food and Drug Administration.

The products are being recalled because our testing has found these lots to be superpotent. The product may have up to 115.0% of the labeled amount of Liothyronine (T3). The batches were distributed by Acella Pharmaceuticals, LLC from **09/06/2018 through 05/22/2019; lot-specific distribution dates can be found below:**

Product	NDC	Lot #	Distribution Dates
NP Thyroid® 30 mg	42192-329-01	M329A19-1	04/02/2019 – 05/22/2019
		M329H18-1	10/19/2018 – 11/19/2018
		M329J18-1	11/19/2018 – 01/29/2019
		M329J18-2	11/27/2018 – 01/09/2019
		M329J18-3	11/20/2018 – 01/03/2019
		M329M18-2	01/25/2019 – 04/22/2019
NP Thyroid® 60 mg	42192-330-01	M330J18-2A	11/12/2018 – 11/27/2018
		M330J18-3	11/27/2018 – 12/12/2018
NP Thyroid® 90 mg	42192-331-01	M331G18-1	09/06/2018 – 09/26/2018
		M331J18-1	11/12/2018 – 12/11/2018
		M331J18-2	11/12/2018 – 12/11/2018
		M331M18-1	02/06/2019 – 03/07/2019
		M331M18-2	02/18/2019 – 03/06/2019

42192-00278-01000384
DROGUERIA BETANCES, LLC
AVE LUIS MUNOZ MARIN ESQ. TROCHE ANGORA EL TROCHE,
BO TOMAS DE CASTRO PO BOX 368
CAGUAS, PR 00725

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PHARMACEUTICALS, LLC

Acella Pharmaceuticals, LLC requests that you immediately take the following actions:

- Examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

- In the event you have the Recalled product, please return to Qualanex, LLC., using the enclosed Postage Paid Product Return label and mail to the following:

  Qualanex, LLC.
  1410 Harris Road
  Libertyville, IL 60048

- Please return the enclosed Business Response Form via fax to 847-737-3719 or email to Recall@qualanex.com.

This action applies only to the NP Thyroid® NDCs and 13 lots listed above. Only product from these lots will be accepted under the terms of this recall.

If you have any general questions regarding the return of this product please contact Qualanex via email at recall@qualanex.com or call 888-280-2042 (Monday through Friday from 8:00 am to 5:00 pm ET).

If you have any medical questions regarding this recall, please contact Acella Pharmaceuticals, LLC at 470-550-1551 (Monday through Thursday from 9:00 am to 5:00 pm or Friday from 9:00 am to 12:30 pm ET).

We regret any inconvenience and appreciate your immediate cooperation.

Art Deas
Chief Executive Officer

For Acella Pharmaceuticals, LLC.

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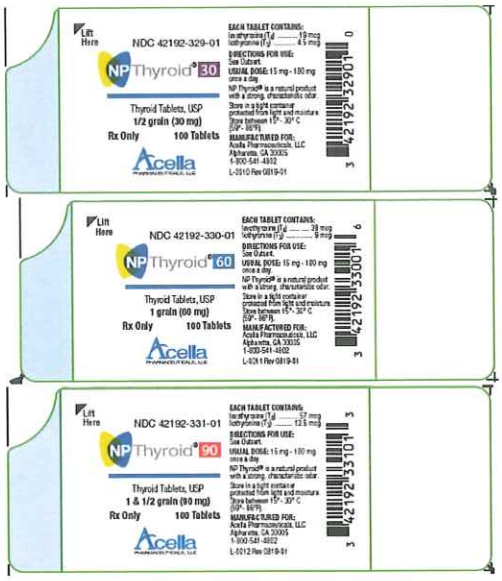
See below for product labels and product images:



NP Thyroid® 30 mg	NP Thyroid® 60 mg	NP Thyroid® 90 mg
		

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URGENT DRUG RECALL
BUSINESS RESPONSE FORM

05/28/2020

Product	NDC	Lot #	Exp. Date
NP Thyroid 30 mg	42192-329-01	M329A19-1	20-Dec
		M329H18-1	20-Jul
		M329J18-1	20-Aug
		M329J18-2	20-Aug
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		M329M18-2	20-Nov
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		M331J18-1	20-Aug
		M331J18-2	20-Aug
		M331M18-1	20-Nov
		M331M18-2	20-Nov

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the withdrawal instructions and have taken the appropriate action.

Customer Name _____ DEA #_____

DEA # is required, if it is not provided, the processing of your form will be delayed.

Address_____

City_____ State_____ Zip_____

Contact Name (please print)_____ Telephone #_____

Fax # _____

Contact Email _____

Contact Signature _____ Date_____

[ ] I have read and understand the recall instructions provided in the letter.

[ ] I have identified and notified my customers that were shipped this product.

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I have checked my stock and:

[ ] Do not have any stock of the recalled items.

OR

[ ] I have quarantined and listed in the table below the quantity of recall units I will be returning to QUALANEX as soon as possible. Upon receipt of this Response Form, QUALANEX will issue a Return Authorization to be included with the product.

Product Description	NDC	Lot Numbers	Sealed bottle quantity to be returned	Open bottle quantity to be returned

If you did not purchase the product directly from the Manufacturer, please complete the below section.

Purchased From: Wholesaler Name _____Wholesaler DEA#_____

Any adverse events associated with recalled/failed product? No [ ] Yes [ ] If yes, please explain:

_____

_____

If you have any questions regarding this form or product return please contact QUALANEX at 888-280-2042, Office hours 8:00 am – 5:00 pm ET Monday thru Friday.

Please fax this form to: 847-737-3719 or E-mail recall@qualanex.com

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