September 18, 2020 **COM-2020-067**

RECALL NOTIFICATION

FDA PUBLICATION DATE:

September 17, 2020

DRUG NAME: NP Thyroid® 15 and NP Thyroid® 120

COMPANY: Acella Pharmaceuticals, LLC.

REASON: Sub potent products as low as 87% of the labeled amount of levothyroxine.

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on September 17, 2020, the US Food and Drug Administration (FDA) published a safety communication for NP Thyroid® 15 and NP Thyroid® 120 indicating the products have a lower potency than the labeled of Levothyroxine (T4). The products recalled were packed in 100-count bottles.

Product	NDC	Lot Number	Exp. date
NP Thyroid® 15 (15 mg)	42192-327-01	M327E19-1	10/2020
NP Thyroid® 120 (120mg)	42192-328-01	M328F19-3	11/2020

Patients with hypothyroidism may experience symptoms of uncontrolled disease. Patients at high risk for serious injury include the elderly, pregnant women, and newborn infants.

Pharmacy required actions(s):

- Identify if the product is inventory and immediately stop using and dispensing it.
- Contact all patients that, in the previous 90 days, received the recalled medication.

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

- Advise patient that should not discontinue use of the drug without contacting their healthcare provider for guidance or a replacement prescription.
- Contact Acella Pharmaceuticals at 1-888-280-2044 for the questions about the recalled product or via email at recall@acellapharma.com.

Contact information:

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at:

- FDA Recall for NP Thyroid 15 and NP Thyroid 120
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. Also, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (, 2020). Acella Pharmaceuticals, LLC Issues Voluntary Nationwide Recall of Two Lots of NP Thyroid®, Thyroid Tablets, USP Due to Sub Potency. Retrieved September 18, 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-two-lots-np-thyroidr-thyroid-tablets

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com