COMPANY ANNOUNCEMENT

Acella Pharmaceuticals, LLC Issues Voluntary Nationwide Recall of Two Lots of NP Thyroid®, Thyroid Tablets, USP Due to Sub Potency

Summary

Company Announcement Date:

September 17, 2020

FDA Publish Date:

September 17, 2020

Product Type:

Drugs

Reason for Announcement:

Sub Potency

Company Name:

Acella Pharmaceuticals, LLC

Brand Name:

NP Thyroid 15 & NP Thyroid120

Product Description:

Thyroid Tablets

Company Announcement

Acella Pharmaceuticals, LLC is voluntarily recalling one lot of 15-mg and one lot of 120-mg NP Thyroid®, Thyroid Tablets, USP [levothyroxine (T4) and liothyronine (T3)] to the consumer level. The products are being recalled because testing has found these lots to be sub potent. The product may have as low as 87% of the labeled amount of levothyroxine (T4). More information can be found at www.npthyroid.com/product-updates (//www.npthyroid.com/product-updates) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Risk Statement: Patients being treated for hypothyroidism (underactive thyroid), who receive sub potent NP Thyroid®, may experience signs and symptoms of hypothyroidism (underactive thyroid) which may include, fatigue, increased sensitivity to cold, constipation, dry skin, puffy face, hair loss, slow heart rate, depression, swelling of the thyroid gland and/or unexplained weight gain or difficulty losing weight. There is reasonable risk of serious injury in newborn infants or pregnant women with hypothyroidism including early miscarriage, fetal hyperthyroidism, and/or impairments to fetal neural and skeletal development. In elderly patients and patients with underlying cardiac disease toxic cardiac manifestations of hyperthyroidism may occur, such as cardiac pain, palpitations or cardiac arrhythmia. To date, Acella has received four reports of adverse events for these lot numbers possibly related to this recall.

NP Thyroid®, Thyroid Tablets, USP is composed of levothyroxine and liothyronine, and used to treat hypothyroidism (underactive thyroid). The products subject to recall are packed in 100-count bottles. See product images.

To best identify the product, the NDC's, Product Description, Lot Numbers and Expiration Dates are listed. These lots were distributed nationwide in the USA to Acella's direct accounts, including wholesalers, pharmacies, and healthcare offices. Additionally, consumers may be able to determine that their product is not impacted by the recall if the "use by," "discard after," or "expiration date" on their prescription bottle is on or after December 2020.

Product	NDC	Lot #	Exp. Date
NP Thyroid® 15, Thyroid Tablets, USP, ¼ grain (15 mg)	42192-327-01	M327E19-1	October 2020
NP Thyroid® 120, Thyroid Tablets, USP, 2 grain (120 mg)	42192-328-01	M328F19-3	November 2020

See Product Labels:

Acella is proactively notifying its wholesalers by email and phone to discontinue distribution of the two above referenced lots being recalled and is arranging for return of all recalled products. Patients who are currently taking NP Thyroid® from the lots being recalled should not discontinue use without contacting their healthcare provider for further guidance and/or a replacement prescription.

Consumers with questions about the recall can email Acella Pharmaceuticals at recall@acellapharma.com (mailto:recall@acellapharma.com) or contact our representatives at 1-888-280-2044, Monday through Friday from 8:00 am to 5:00 pm ET. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

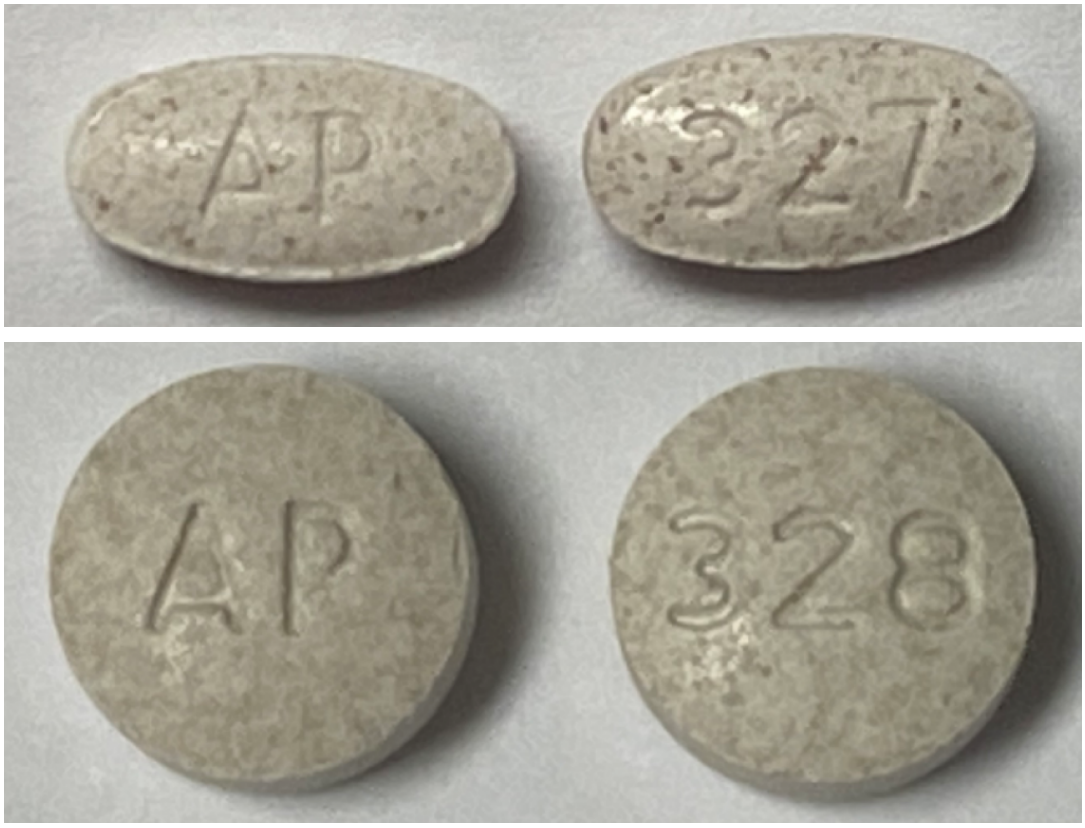
Consumers:

Acella Pharmaceuticals

1-888-280-2044

recall@acellapharma.com (mailto:recall@acellapharma.com)

Product Photos



More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)