



Clifton Health Department Food Recall Notification



Food/Drug/Pet Recall: RLC Labs, Inc.

RLC Labs, Inc. is voluntarily recalling a total of 483 lots of Nature-Throid® and WP Thyroid® in all strengths, all counts of product within current expiry to the consumer level. The products are being recalled because testing of samples from six (6) lots by the U.S. Food and Drug Administration found the samples to be sub potent. The product may have as low as 87% of the labeled amount of Liothyronine (T3) or Levothyroxine(T4).

Risk Statement: Patients being treated for hypothyroidism (underactive thyroid), who receive sub potent Nature-Throid® or WP 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. RLC Labs, Inc. has not received any reports of adverse events related to this recall.

Nature-Throid® and WP Thyroid® (thyroid tablets, USP) is composed of liothyronine and levothyroxine, and are used to treat hypothyroidism (underactive thyroid). The products subject to recall are packaged in 30, 60, 90, 100 and 1,000 count bottles.

To best identify the product, the NDC's, Product Descriptions, Lot Numbers and Expiration Dates are listed in the below documents. These lots were distributed nationwide in the USA to RLC Labs, Inc.'s direct accounts, including healthcare professionals and retail pharmacies.

RLC Labs, Inc. is proactively notifying its wholesalers by email, mail and phone to discontinue distribution of the product being recalled and is arranging for the return of all recalled products. Patients who are currently taking Nature-Throid® and WP Thyroid® should not discontinue use without contacting their healthcare provider for further guidance and/or replacement prescription.

Consumers with questions about the recall can email RLC Labs, Inc. at recall@rlclabs.com or contact RLC Labs, Inc. Customer Service at 1-877-797-7997, Monday through Thursday from 7:00 am to 4:00 pm MST (AZ) and Friday from 7:00 am to 3:00 pm MST (AZ).

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



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fax.

- . Complete and submit the report Online
- . Regular Mail or Fax: Download form 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.