

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Accord Healthcare, Inc. ("Accord Healthcare") is recalling one lot of Levothyroxine Sodium Tablets USP 300 mcg, at the Pharmacy Level.

This recall is being initiated because out of specification result was observed during long term stability testing of Levothyroxine Sodium Tablets USP for 300 mcg. The out-of-specification result was observed on an assay conducted on one lot of Levothyroxine Sodium Tablets.

The assay content of Levothyroxine Sodium Tablets for lot D2401522 (300 mcg, 94.5% at 18 months) was observed below the approved specification range of 95.0%-105.0% set forth on the label. This means that the observed level of active ingredients in the product was below the approved specification.

This may affect the efficacy of the medication. As patient safety is the highest priority, Accord Healthcare is taking immediate action to recall the affected product lot.

PRODUCT: Levothyroxine Sodium Tablets USP for 300 mcg, 90 count

NDC NUMBER: 16729-458-15

LOT NUMBER: D2401522

EXPIRY DATE: 06/2026

DISTRIBUTION DATES: 11/07/2024 to 06/04/2025