*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.*

Acella Pharmaceuticals, LLC is initiating a retail/pharmacy level recall for two lots of Naproxen Oral Suspension, USP, 125 mg/5 mL. This recall is being conducted with the knowledge of the Food and Drug Administration. The impacted lot numbers can be found in the table below.

The product is being recalled because product testing found levels of lead and lithium in the product above the International Council for Harmonisation (ICH) established permitted daily exposure limits.

Exposure to low levels of lead may not elicit any symptoms. High levels of exposure to lead in utero, infancy, and early childhood can lead to neurological effects such as learning disabilities, behavior difficulties, and lowered IQ. The very young are particularly vulnerable to the potential harmful effects from lead exposure because of their smaller body sizes and rapid metabolism and growth. For adults, chronic lead exposure is associated with kidney dysfunction, hypertension, and neurocognitive effects.

Exposure to lithium may result in increased risk of reduced urinary concentrating ability, hypothyroidism, hyperparathyroidism, and weight gain.

The lots were distributed by Acella Pharmaceuticals, LLC from **06/21/2023 and 10/20/2025.**

| **Product Description** | **NDC Number** | **Lot Number** | **Exp. Date** | **Distribution Dates** |
|---|---|---|---|---|
| Naproxen Oral Suspension, USP, 125 mg/5 mL | 42192-619-16 | 23F02 | 05/2026 | 06/21/2023 – 03/17/2025 |
| Naproxen Oral Suspension, USP, 125 mg/5 mL | 42192-619-16 | 25A37 | 01/2028 | 03/18/2025 – 10/20/2025 |