

## KinderFarms Voluntarily Recalls all KinderMed Pain & Fever Products Due to Acetaminophen Instability

Date: 11/17/2023

At Magellan Medicaid Administration, we want to help you receive the best possible care. Visit our drug recall site for details: <a href="https://www1.magellanrx.com/drug-recalls/">https://www1.magellanrx.com/drug-recalls/</a>.

## About this recall:

KinderFarms is voluntarily recalling *all lots* of KinderMed *Infants'* Pain & Fever oral suspension (160 mg/5 mL of acetaminophen; NDC 82673-0096-02) and KinderMed *Kids'* Pain & Fever oral suspension (160 mg/5 mL of acetaminophen; NDC 82673-0097-04) to the retail and consumer level. These over-the-counter (OTC) products are being voluntarily recalled due to acetaminophen instability as testing showed some lots were not within range and thereby may pose a health risk.

Acetaminophen is the active ingredient in many pain-relieving medicines.

## What this means to you:

As a result of acetaminophen levels being outside of the expected range, the product may lead to adverse effects, such as stomach pain, nausea, vomiting, or jaundice (yellowing of the skin or eyes) at higher doses. The company has not received any reports of serious adverse events from either of these products to date. No other KinderFarms products are impacted by this recall.

Consumers who purchased either of these products should stop using them and may return the product to the place of purchase for a full refund. Consumers with questions may contact the company at consumerrelations@kinderfarms.com or 800-996-2930 from 6:00 AM to 5:00 PM (Pacific Time).

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.
- Regular Mail or Fax: <u>Download form</u> 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 United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: <a href="https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kinderfarms-llc-voluntarily-recalling-all-kindermed-pain-fever-products-due-acetaminophen">https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kinderfarms-llc-voluntarily-recalling-all-kindermed-pain-fever-products-due-acetaminophen</a>

FDA contact information for reporting adverse events/quality complaints can be reached online at <a href="https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home">https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home</a> or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.