carecentrix

Provider Newsflash
September 2026

FDA Recall – American Regent, Inc. Epinephrine Injection, USP 30 mg/30 mL (1 mg/mL)

Purpose of this communication:

We are writing to inform you We are writing to inform you that the FDA has issued a voluntary nationwide recall of three lots of American Regent, Inc. Epinephrine Injection, USP 30 mg/30 mL (1 mg/mL) multi-dose vials due to particulate matter and lack of assurance of sterility. The affected NDC is 0517-3030-01 and the affected lot numbers are 25128L1C0, 25280L1C0, and 26108L1C0. The product is indicated for emergency treatment of allergic reactions, including anaphylaxis, and to increase mean arterial blood pressure in adults with hypotension associated with septic shock. Particulate matter may cause blockage or clotting in blood vessels, pulmonary embolism, organ damage or death, vein irritation, inflammatory reactions, aggravation of preexisting infections, or allergic reactions. Cracked vials may compromise container integrity, resulting in contamination and loss of sterility. No adverse events related to this recall had been reported at the time of the notice. American Regent is arranging return or replacement of recalled product. Distributors, retailers, and healthcare facilities should stop using affected product and return it to the place of purchase or discard it.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-regent-inc-issues-voluntary-nationwide-recall-three-lots-epinephrine-injection-usp-30-mg-30
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.