

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
American Regent Initiates Voluntary Nationwide Recall of
Dexamethasone Sodium Phosphate Injection, USP, 4 mg/mL, 1 mL Single Dose Vials;
5 mL and 30 mL Multiple Dose Vials**

SOURCE: Luitpold Pharmaceuticals, Inc.

Dexamethasone Sodium Phosphate Injection, 4 mg/mL, 1 mL Single Dose Vials (NDC # 0517-4901-25); Dexamethasone Sodium Phosphate Injection, 4 mg/mL, 5 mL Multiple Dose Vials (NDC # 0517-4905-25); Dexamethasone Sodium Phosphate Injection, 4 mg/mL, 30 mL Multiple Dose Vials (NDC # 0517-4930-25)

PLEASE NOTE: This voluntary recall, initiated on March 16, 2011 to the User Level, is for ALL unexpired lots of all 3 sizes of Dexamethasone Sodium Phosphate Injection, USP. See Appendix for lot numbers, expiration dates and dates of first distribution.

This voluntary recall was initiated because some vials of these lots either contain particulates or have the potential to form particulates prior to their respective expiration dates. Potential adverse events after intravenous administration of solutions containing particulates, may include disruption of blood flow within small blood vessels in the lung, localized inflammation (swelling and redness due to accumulation of inflammatory cells), and granuloma formation. Intramuscular administration could result in foreign body inflammatory response, with local pain, swelling and possible long term granuloma formation. American Regent is undertaking this recall in consideration of the potential for safety issues, if these lots of product are administered to patients. The product was distributed to wholesalers and distributors nationwide.

Hospitals, emergency rooms, infusion centers, clinics, physician offices and other healthcare providers and facilities should not use American Regent Inc., Dexamethasone Sodium Phosphate Injection, USP 4mg/mL, 1mL Single Dose Vials, 5mL and 30 mL Multiple Dose Vials with the lot numbers listed in the Appendix for patient care and should immediately quarantine any product for return.

While American Regent continues to investigate this issue, the company is taking precautionary action and initiated this voluntary nationwide recall. American Regent has informed the FDA of its actions and is maintaining ongoing discussions with the agency.

Additional information including an Appendix with lot numbers and recommendations for reporting and returning product is available at:

<http://www.fda.gov/Safety/Recalls/ucm247526.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at

<http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.