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IMPORTANT DRUG ADMINISTRATION INFORMATION

November 1, 2011

**Re: Ammonium Molybdate Injection, USP
250 mcg/10 mL (25 mcg/mL) 10 mL Single Dose Vial
NDC# 0517-6610-25**

Dear Healthcare Professional:

American Regent, Inc. is informing Healthcare Professionals that all lots of Ammonium Molybdate Injection, USP, Single Dose Vials, in commercial distribution have the potential for visible particulate matter. Retention samples of lots of product already in commercial distribution have been visually re-inspected and have not exhibited any evidence of visible particulate matter.

However, as a precautionary measure, American Regent advises that a filter must be used for the withdrawal and administration of all lots of this product.

The following procedure must be used for the compounding and administration of ALL lots of Ammonium Molybdate Injection, USP:

1. Perform a visual inspection on the vial prior to withdrawal of the contents.
**DO NOT USE IF PARTICULATES ARE OBSERVED. DISCARD.
USE A NEW VIAL.**
2. Use a 5 micron filter needle to withdraw the required calculated volume of Ammonium Molybdate Injection, USP.
3. Remove the filter needle and attach a standard needle to the syringe before adding to a larger volume of IV fluid and prior to patient administration.
NOTE: Ammonium Molybdate Injection, USP is indicated for use as a supplement to TPN (Total Parenteral Nutrition) solutions. Aseptic addition of Ammonium Molybdate Injection, USP to TPN solutions under a laminar flow hood is recommended.
4. Visually inspect the final IV admixture solution.
**DO NOT USE IF PARTICULATES ARE OBSERVED. DISCARD.
USE A NEW VIAL.**
5. Use a 0.22 micron in-line filter when administering the final IV admixture to patients.
6. For lipid containing admixtures, the use of a 1.2 micron in-line filter is recommended.

If particulates are observed, or if you require additional information, please contact the Professional Services Department at 1-877-788-3232 (Monday-Friday: 9:00 am-5:00 pm ET) or e-mail at: inquiry@americanregent.com.

Potential adverse events after intravenous administration of particulates include damage to blood vessels in the lung, localized swelling, and granuloma formation.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Reporting program online, by regular mail, or by fax.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form
- **Fax:** 1-800-FDA-0178

We apologize for any inconvenience that you may experience and appreciate your cooperation in this matter.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Walter M.", is centered on a light gray rectangular background.

Walter A. Tozzi, R.Ph., MS, MBA
Sr. Director of Marketing & Professional Services