January 31, 2013

IMPORTANT DRUG ADMINISTRATION INFORMATION

READ PRIOR TO USE OF THIS PRODUCT

Re: Possible discoloration and particulates in certain lots of EPINEPHRINE INJECTION, USP PRESERVATIVE FREE, SULFITE FREE, 1 mg/mL ampule NDC 0517-1071-25

Dear Healthcare Professional:

The purpose of this letter is to inform you that several lots of Epinephrine Injection, USP, 1 mg/mL ampules manufactured by Luitpold Pharmaceuticals, Inc. and distributed by American Regent, Inc. (Shirley, NY) may show evidence of discoloration either alone or in combination with 'smoke-like' precipitate. Retention samples of several lots of this product have been visually re-inspected and have exhibited visible evidence of discoloration and visible particles that dissipate upon agitation.

The discoloration and precipitate both have been related to the degradation of Epinephrine. The level of degradation is at trace levels, and laboratory testing of ampules that are discolored or show presence of precipitate has confirmed that assay and impurity levels are acceptable. Lots that are being newly released have been re-inspected to remove any affected ampules.

Directions for Healthcare Professionals

As a precautionary measure, American Regent advises that all ampules of Epinephrine Injection, USP, l mg/mL (Preservative Free and Sulfite Free) be visually inspected prior to use. DO NOT USE IF DISCOLORATION AND/OR PARTICULATES ARE PRESENT. USE A NEW AMPULE.

If the product is to be administered as an IV push, intramuscular, intracardiac or subcutaneous injection, visually inspect ampule prior to use. DO NOT USE IF DISCOLORATION AND/OR PARTICULATES ARE PRESENT. USE A NEW AMPULE.

If the product is to be administered intraspinally, visually inspect ampule prior to use **and** visually inspect the final admixture prior to patient administration. DO NOT USE IF DISCOLORATION AND/OR PARTICULATES ARE PRESENT. DISCARD ADMIXTURE.

If the product is to be administered ophthalmologically, visually inspect ampule prior to use **and** visually inspect the final ocular admixture solution prior to patient administration. DO NOT USE IF DISCOLORATION AND/OR PARTICULATES ARE PRESENT. DISCARD ADMIXTURE.

If ampules showing evidence of discoloration and/or precipitate are observed, or if you require additional information, please contact American Regent at 1-877-788-3232 then press 2 for the Professional Services Department (Monday-Friday: 9:00am-5:00pm ET) or via e-mail at inquiry@americanregent.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, telephone, or 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: MedWatch, 5600 Fishers Lane, Rockville, MD 20857
- **Telephone**: 1-800-332-1088
- **Fax:** 1-800-FDA-0178