Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Advanced Pharma, Inc. D/B/A Avella of Houston Issues Voluntary Nationwide Recall of All Unexpired Nitroglycerin Injection In 5% Dextrose USP Products Produced At Its Houston Location From March 3, 2017 Through May 31, 2017 Due To Sub-Potency

For Immediate Release

June 15, 2017

Contact

Consumers

Advanced Pharma, Inc.
(877) 292-4323

Announcement

Advanced Pharma, Inc. d/b/a Avella of Houston ("Advanced Pharma") is voluntarily recalling all unexpired lots of Nitroglycerin products that were produced at Advanced Pharma's Houston location between March 3, 2017 and May 31, 2017 to the hospital/user level. The recall is being issued based on laboratory test results indicating a lower than expected potency on certain lots of compounded NitroGlycerin Injection which would lead to a lower dose being administered. While the lower than expected potency results affected only certain lots of Nitroglycerin, in an abundance of caution, **Advanced Pharma is recalling all unexpired lots of NitroGlycerin. To date, Advanced Pharma has not received any reports of product complaints and/or adverse events related to the products.**

Although nitroglycerin is titrated based on clinical response, an extreme and unexpected reduction in dose than expected could lead to a delay in treatment, disruption of clinical care of the patient, and worsening of patient's conditions.

Nitroglycerin Injection in 5% Dextrose, USP is indicated for treatment of high blood pressure before, during or after surgery; for control of heart failure after a heart attack; for treatment of heart related chest pain in patients who have not responded to nitroglycerin tablets taken under the tongue and other heart medicines; and to lower blood pressure during surgery. The recalled NitroGlycerin products include the 100 mcg per mL and 200 mcg per mL strengths available in 5 mL, 10 mL, and 20 mL sterile single dose syringes and are packaged in various sizes per carton. These products were not distributed directly to patients or consumers, but rather to healthcare facilities (e.g. hospitals) nationwide in the USA between March 9, 2017 to June 1, 2017 and have expiration dates (also known as "Beyond Use Dates" or "BUD") ranging from June 9, 2017 to August 15, 2017. **The issue is segregated to the Houston location and no other Avella locations are involved or affected**.

Advanced Pharma has notified impacted customers of the voluntary recall by phone, email and overnight mail. Customers that have any of the affected medications that are being recalled should immediately discontinue use and return the unused portion to Avella. Customers with any of the affected medications can also reference Advanced Pharma's website for more information on the specific lot numbers affected, pictures of the product labels at issue and forms and contact information: **avella.com/ap-nitroglycerin-recall (http://avella.com/ap-nitroglycerin-recall)**. For a full list of products, please visit **https://www.avella.com/sourceb-products (https://www.avella.com/sourceb-products)**.

Patients and healthcare providers with questions regarding this recall can contact the Advanced Pharma, Inc. recall line at (877) 292-4323, Monday through Friday, between 6am and 6pm Pacific Standard Time or via e-mail at **ProductRecall@avella.com (mailto:ProductRecall@avella.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 either online, by regular mail or by fax.

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** 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 U.S. Food and Drug Administration.

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