FUSION IV Pharmaceuticals, Inc dba. AXIA Pharmaceutical is voluntarily recalling all unused sterile drug products within expiry, to the user level, due to a lack of assurance of sterility. The recalled sterile products have been found to be inconsistent with federal guidelines.

Administration of a drug product intended to be sterile that is not sterile could result in serious infections which may be life-threatening. To date, FUSION IV Pharmaceuticals, Inc dba. AXIA Pharmaceutical has not received any reports of adverse events related to this recall and is recalling all sterile products out of an abundance of caution and to promote patient safety, which is AXIA pharmaceutical's highest priority.

For a full listing of the products, including lot numbers and expiration dates, being recalled, please follow this link: <u>http://www.axiapharma.net/recalls.html</u>. Sterile drug product was distributed nationwide to consumers.

FUSION IV Pharmaceuticals, Inc dba. AXIA Pharmaceutical is notifying its customers by letter and direct outreach. FUSION IV Pharmaceuticals, Inc dba. AXIA Pharmaceutical is arranging for the return of all recalled products. Customers that have any recalled products should stop using and return to FUSION IV Pharmaceuticals, Inc dba. AXIA Pharmaceutical.

Consumers with questions regarding this recall can contact FUSION IV Pharmaceuticals, Inc dba. AXIA Pharmaceutical Erdwin Orellana by phone number: (877-685-8222) or e-mail address <u>ecallassistance@axiapharma.net</u>, Monday through Friday: 8:00 AM to 4:00 PM PST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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
- Regular Mail or Fax: <u>Download form</u> 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.

Link to Products List.

This <u>company announcement</u> is posted by the Food and Drug Administration (FDA).