FDA NEWS RELEASE

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FDA reminds health care providers not to use sterile products from NuVision Pharmacy

Products may still pose serious risk to patients

The U.S. Food and Drug Administration is reminding health care providers about safety concerns with all sterile drug products made and distributed by NuVision Pharmacy of Dallas, Texas. Health care providers should not administer any NuVision Pharmacy sterile products to patients because the products' sterility is not assured.

This alert follows the FDA's notice on May 18, 2013 recommending that health care providers and other health care professionals, including hospital staff, immediately check their medical supplies for NuVision Pharmacy sterile products, quarantine those products, and not administer them to patients.

NuVision Pharmacy has repeatedly declined to recall its sterile products. The FDA most recently issued a letter to NuVision on July 26, 2013, requesting an immediate recall of all lots of sterile products that have not passed their expiration dates produced at NuVision. In the letter, the FDA outlined poor sterile production practices observed by FDA investigators during an April 2013 inspection of NuVision's Dallas facility. The FDA explained that those practices raised concerns about a lack of sterility assurance of NuVision's sterile drug products. The FDA noted that if a drug product marketed as sterile contains microbial contamination, patients could be at risk for serious, potentially life-threatening infections.

NuVision responded to the letter by refusing to recall its sterile products. Under its authority, the FDA cannot require NuVision to undertake such a recall. Therefore the agency reminds health care providers not to use any sterile products from NuVision.

In April 2013 NuVision recalled methylcobalamin injection and lyophilized injection products due to a lack of sterility assurance and concerns associated with the quality control processes identified during the FDA's April 2013 inspection. The FDA received adverse event reports of fever, flu-like symptoms, and soreness at the injection site associated with the methylcobalamin injection product that was previously recalled. The agency is not aware of any adverse event reports associated with other sterile products from NuVision.

Patients who were administered any sterile drug product produced and distributed by NuVision and who have concerns should contact their health care provider. The FDA asks health care providers and consumers to report adverse reactions or quality problems experienced with the use of any NuVision product to the FDA's MedWatch Adverse Event Reporting program by:

- completing and submitting the report online at www.fda.gov/medwatch/report.htm; or
- downloading and completing the form, then submitting it via fax to 1-800-FDA-0178.

In Missouri, any cases of illness suspected of being associated with sterile drug products made and distributed by NuVision Pharmacy should be reported to the Missouri Department of Health and Senior Services (DHSS) at 800/392-0272. Questions should be directed to DHSS' Bureau of Communicable Disease Control and Prevention at 573/751-6113, or 800/392-0272 (24/7).