FDA: Ameridose issues voluntary recall of all products

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(HealthDay)—Ameridose, a Massachusetts-based manufacturer of sterile injectable products and oral syringes, is undergoing a voluntary recall of all unexpired products in circulation, according to an Oct. 31 news release issued by the U.S. Food and Drug Administration.

As yet, no patients have been reported to have experienced infections or other complications in association with Ameridose products. The recall was prompted out of concern that sterility assurance for products made and distributed by the facility is lacking. This concern was raised by the preliminary findings of an FDA investigation of the manufacturer's facility as part of an ongoing investigation into the fungal meningitis outbreak linked with Ameridose's sister company, the New England Compounding Center of Framingham, Mass.

Acknowledging that the recall stems from an abundance of caution rather than an actual adverse event, the FDA is not at this time recommending that physicians follow up with patients who have received Ameridose products, only that they stop using these products and return them. Hospitals, clinics, and other customers with Ameridose products can call the company at 888-820-0622 for guidance on returning the products.

"The FDA's top priority is to ensure that drugs are safe for the American public," Margaret A. Hamburg, M.D., FDA Commissioner, said in a statement.

More information: More Information