Health Advisory:

FDA Reports Voluntary Recall of All Ameridose Drug Products

November 1, 2012

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FROM: **MARGARET T. DONNELLY**
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SUBJECT: **FDA Reports Voluntary Recall of All Ameridose Drug Products**

The U.S. Food and Drug Administration (FDA) announced today that Ameridose, LLC, based in Westborough, Mass., is voluntarily recalling all of its unexpired products in circulation. Ameridose is a company sharing common management by the same parties as New England Compounding Center (NECC) of Framingham, Mass., the firm associated with compounded drugs linked to the ongoing fungal meningitis outbreak.

Products from Ameridose can be identified by markings that indicate Ameridose by name or by its company logo. A complete list of all products subject to this recall can be accessed at www.ameridose.com.

This recall is not based on reports of patients with infections associated with any of Ameridose's products, and the agency recommended this recall out of an abundance of caution. Therefore, at this time, the FDA is also recommending that health care professionals do not need to follow up with patients who received Ameridose products. Health care professionals should stop using Ameridose products at this time, and return them to the firm.

Hospitals, clinics, health care professionals, and other customers with Ameridose products on hand should immediately examine their inventory and quarantine products subject to this recall. The company has stated that if products are found, a form regarding the current status of these products, which is available at http://cdn-ecomm.dreamingcode.com/public/195/documents/Version-20121031131927-Documents-195-1701-1.doc, should be completed and returned to Ameridose by fax at 508-656-6596, or by email at amdservice@ameridose.com. The company then will contact you to arrange for return of all materials. If there are questions about the recall, the company can be contacted at 888-820-0622 on Monday through Friday from 9:00 am to 5:00 pm EST, or by email at amdservice@ameridose.com.

In addition, health care professionals and patients may dial the FDA's Drug Information Line at 855-543-DRUG (3784) and press * to get the most recent information regarding the Ameridose recall and speak directly to a pharmacist.

Background

The FDA is currently conducting an inspection of Ameridose's facility. Although this inspection is ongoing, the FDA's preliminary findings have raised concerns about a lack of sterility assurance for products produced at and distributed by this facility. Use of non-sterile injectable products can represent a serious hazard to

health that could lead to life-threatening injuries. Most products produced at and distributed by this facility are represented by Ameridose to be sterile products. Ameridose entered into a voluntary agreement with the Massachusetts Board of Registration in Pharmacy to cease all pharmacy and manufacturing operations starting on Oct. 10, 2012.

Together with the State of Massachusetts, the FDA commenced the current inspection of the Ameridose facility as part of the agency's ongoing fungal meningitis outbreak investigation. Ameridose is a company sharing common management by the same parties as New England Compounding Center (NECC) of Framingham, Mass., the firm associated with compounded drugs linked to the ongoing fungal meningitis outbreak.

"Because the preliminary results of the FDA's inspection raise concerns about the sterility assurance of Ameridose's products, the FDA is advising health care professionals to stop using all Ameridose products and follow the recall procedures provided by the firm," explained Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research.

The FDA has identified some Ameridose products that currently appear on the critical shortage list. These products were in shortage before the Ameridose recall, but supplies may be further affected as a result of the Ameridose recall. The FDA is working with alternative manufacturers to maintain supplies of these life-saving drugs.

"The agency is taking all steps within its authority to help prevent or alleviate shortage situations and to minimize the impact this recall may have on drug supplies," stated FDA Commissioner Margaret A. Hamburg, M.D.

As new information becomes available, the FDA will issue additional public communications.

The FDA asks health care professionals and consumers to report any adverse reactions to the FDA's MedWatch Program by fax at 800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch[4].

Distribution information for these products is not available at this time. As Missouri distribution can not be ruled out, please check your inventories for these recalled products.

Sources:

Ameridose Issues Recall of All Products
http://www.fda.gov/Safety/Recalls/ucm326349.htm

FDA reports voluntary recall of all Ameridose drug products
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm326361.htm