KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health

EDMUND G. BROWN JR.
Governor

AFL 12-52

November 7, 2012

TO: All Facilities

SUBJECT: Ameridose Issues Recall of All Products

The California Department of Public Health is advising all facilities to take the following actions based on an urgent message from the Food and Drug Administration (FDA):

Ameridose has announced it will commence a voluntary recall of any unexpired products remaining in circulation. The full list of Ameridose products can be found here:

Ameridose Voluntary Recall Product List

As a result of its on-going inspection of the Ameridose facility, the FDA will be seeking improvements in Ameridose's sterility testing process. Ameridose has not received any adverse reports related to the products subject to this recall. Neither Ameridose nor the FDA has identified impurities in any Ameridose products. Nevertheless, out of an abundance of caution Ameridose is undertaking this recall.

Ameridose is notifying its customers by fax and is arranging for return of all recalled products. Customers that have Ameridose products which are affected by this recall should immediately examine their inventory and quarantine products subject to this recall, complete the form regarding the current status of these products, and return the form to Ameridose by fax at 508-656-6596, or by email at amdservice@ameridose.com. Copies of the recall letter and form are available on the Ameridose website: (www.ameridose.com).

Customers with questions regarding this recall can contact Ameridose by phone at 888-820-0622 or by email at amdservice@ameridose.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using Ameridose products.

Healthcare professionals and patients are encouraged to report any adverse reactions or quality problems experienced with the use of Ameridose products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Online: (http://www.fda.gov/medwatch/report.htm)

Regular mail:

Use form FDA 3500 and mail to address on the pre-addressed form. The form can be found at the FDA website: (http://www.fda.gov/medwatch/report.htm) or you may also request this form by calling 1-800-332-1088.

Fax: 1-800-FDA-0178

Thank you for your prompt attention to this matter.

Sincerely,

Original Signed by Debby Rogers

Debby Rogers, RN, MS, FAEN
Deputy Director
Center for Health Care Quality

Center for Health Care Quality, MS 0512 . P.O. Box 997377 . Sacramento, CA 95899-7377
(916) 324-6630 . (916) 324-4820 FAX
Department Website (cdph.ca.gov)

Page Last Updated : October 7, 2017