U.S. Food and Drug Administration

FDA News

FOR IMMEDIATE RELEASE
P02-27
August 14, 2002

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA ISSUES ORDER TO RECALL AND TO PREVENT FURTHER USE OF HUMAN TISSUE PROCESSED AT CRYOLIFE, INC

The Food and Drug Administration (FDA) has ordered Cryolife, Inc. ("Cryolife") of Kennesaw, Ga., a human tissue-processing firm, to recall distributed human tissue processed from October 3, 2001, to the present. Under the order, the firm must also withhold from the market or destroy tissue processed after that date. FDA is taking this action because it has determined that Cryolife cannot ensure that the human tissue it processes for transplantation is free from fungal and bacterial contaminants.

Tissue from a donor processed by Cryolife on and after October 3, 2001, has been associated with the November 7, 2001, death of a patient who received a soft tissue implant during reconstructive knee surgery.

"This order not only protects patients from the unacceptable level of risk associated with tissue processed by Cryolife, it sends a clear signal that FDA stands ready to take whatever action is necessary to ensure the safety of human tissue," said Dr. Lester M. Crawford, FDA Deputy Commissioner.

During its inspection of Cryolife from March 25 through April 12, 2002, FDA found numerous, significant violations of FDA regulations. FDA issued a warning letter to Cryolife on June 17, 2002, after determining, among other things, that the firm had neither adequately investigated its validation of processing and testing methods, nor implemented recommendations from the Centers for Disease Control and Prevention (CDC), or any other procedures, to ensure that tissue processed by the firm is not contaminated.

After determining that Cryolife had failed to take adequate corrective measures to address possible infectious disease contamination of tissue in inventory and distribution, and after reviewing information provided by the firm in response to FDA's warnings, FDA issued the present order.

Current federal regulations for human tissue require firms to prepare, validate, and follow written procedures to prevent infectious disease contamination or cross-contamination during tissue processing. Contamination may be caused by a variety of infectious disease agents including viruses, bacteria, fungi, and transmissible spongiform encephalopathy (TSE)-associated prions.