CryoLife, Inc. Details Responses To The FDA; CryoLife Continues to Submit Validation Data to FDA

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FDA's Order Does Not Affect Heart Valves

ATLANTA, Aug 15, 2002 /PRNewswire-FirstCall via COMTEX/ -- CryoLife, Inc. (NYSE: CRY), a leader in the development and commercialization of living human tissue implantable devices, and a manufacturer and distributor of stentless heart valves and surgical adhesives, today announced a synopsis of CryoLife's recent regulatory events.

December 2001: the FDA inspected CryoLife. This inspection reviewed processes, complaint handling systems, donor screening and microbiological testing. The FDA noted no observations during the December 2001 inspection.

March 8, 2002: the FDA issued a guidance document to all tissue processors, which provided specific agency guidance regarding the validation of procedures to prevent infectious disease contamination or cross contamination between processed tissues.

March 15, 2002: the CDC published an update on orthopedic allograft infections and made numerous recommendations for consideration by CryoLife.

March 25, 2002: CryoLife responded to the CDC by publishing a "White Paper" which described the elements of the CDC recommendations that CryoLife already had in place. The White Paper is available on www.cryolife.com .

March 25, 2002: the FDA initiated an inspection based upon the new guidance that had been published just two weeks prior.

April 12, 2002: the FDA issued a 483 Notice of Observations to CryoLife detailing a number of validation issues to be addressed. Certain validations that CryoLife had conducted were judged inadequate.

May 15, 2002: CryoLife submitted its initial response to the FDA's 483 Notice of Observation. CryoLife's response provided clarifying information, data and a schedule for completing all additional items.

May 17, 2002: CryoLife announced additional measures the company had taken to address infection control, including adopting the CDC's donor refrigeration recommendations and pre-processing microbiological testing.

June 17, 2002: CryoLife, Inc. received a warning letter from the FDA. This letter reiterated many of the observations listed in the 483 Notice of Observations and acknowledged that CryoLife had agreed to provide additional information.

June 25, 2002: CryoLife submitted the Company's follow up responses to the FDA's 483 Notice of Observations. The response included data and a more definitive schedule for ongoing studies.

July 2, 2002: CryoLife submitted a written reply to the FDA's warning letter.

August 13, 2002: CryoLife received its review letter from the FDA. This letter was in response to the Company's submissions and stated that the FDA would call CryoLife to arrange to meet for further discussions.

August 13, 2002: Later that same day, officials from the FDA hand delivered their order for retention, recall, and/or destruction of certain non-valved cardiac tissues, vascular tissues, and orthopedic tissues.

August 15-16, 2002: CryoLife is in the process of submitting certain completed validations to the FDA and anticipates sending them to the FDA either later today or tomorrow.

Additionally, the Company has announced that as part of CryoLife's effort to supplement its validations, cooperate with the FDA and adopt the CDC's recommendations it has further tightened its criteria for discarding donor tissue suspected of being contaminated. CryoLife engaged an outside consultant to advise the Company on scientific and technical issues. CryoLife has contracted with an independent microbiological laboratory to assist the Company in validation testing and has initiated additional in-house studies to improve its processes and test monitoring. CryoLife and the FDA have agreed to meet and discuss further issues after the FDA completes its review of CryoLife's submissions.

Founded in 1984, CryoLife, Inc. is a leader in the development and commercialization of implantable living human tissues for use in cardiovascular, vascular and orthopedic surgeries throughout the United States and Canada. The Company's BioGlue(R) surgical adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels and is CE marked in the European Community and approved in Canada and Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) heart valve and the SynerGraft vascular graft, the world's first tissue-engineered heart valve and vascular replacements, and the CryoLife-O'Brien(R) and CryoLife-Ross(R) stentless porcine heart valves, which are CE marked for distribution within the European Community. The human heart valves processed by CryoLife using the SynerGraft technology are distributed in the U.S. under the trade name CryoValve(R)SG.

For additional information about the company, visit CryoLife's web site: http://www.cryolife.com .

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