SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 5, 2002

CRYOLIFE, INC.
(Exact name of registrant as specified in its charter)

Florida
(State or other jurisdiction of incorporation)

1-13165	59-2417093
(Commission File Number)	(IRS Employer Identification No.)

1655 Roberts Boulevard N.W., Kennesaw, Georgia 30144
(Address of principal executive offices, including zip code)

(770) 419-3355
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

ITEM 5. OTHER EVENTS.

On September 5, 2002, CryoLife, Inc. reached an agreement with the U.S. Food and Drug Administration ("FDA") modifying the FDA's August 13, 2002 Order for Retention, Recall, and/or Destruction. The agreement permits the company to immediately resume processing and limited distribution of its life-saving and limb-saving non-valved cardiac and vascular tissues. It allows CryoLife to distribute existing and newly processed non-valved cardiac conduits and patches, saphenous veins, femoral veins and arteries, and aorto-iliac arteries for specified medically urgent uses when alternative treatments have been exhausted or are unavailable. The Company estimates that most of the covered tissue under its control is used by surgeons under the conditions permitted by the agreement. More information about the agreement is contained in CryoLife's press release dated September 6, 2002, which is incorporated by reference herein and attached as Exhibit 99.1. A copy of the agreement is attached hereto as Exhibit 10.38.

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(a) Financial Statements.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Exhibits.

Exhibit Number	Description

10.38	September 5, 2002 Letter Agreement between CryoLife and FDA permitting limited distribution of certain tissues subject to August 13, 2002 FDA Order
99.1	September 6, 2002 Press Release regarding Letter Agreement with FDA

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, CryoLife has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CRYOLIFE, INC.

Date: September 6, 2002

By: /s/ D. Ashley Lee

Name: D. Ashley Lee
Title: Vice President,
Chief Financial Officer

EXHIBIT INDEX

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10.38	September 5, 2002 Letter Agreement between CryoLife and FDA permitting limited distribution of certain tissues subject to August 13, 2002 FDA Order
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EXHIBIT 10.38

[FDA letterhead]

Steven G. Anderson
President and CEO
CryoLife, Inc.
1655 Roberts Blvd., NW
Kennesaw, GA 30144

Dear Mr. Anderson:

This letter sets forth the entire agreement between CryoLife, Inc. (CryoLife), and the Food and Drug Administration (FDA) pertaining to the disposition of certain human allograft tissues, which are subject to the August 13, 2002, FDA Order for Retention, Recall, and/or Destruction. FDA and CryoLife agree that for the next 45 working days the tissues specified below may be distributed for medically urgent use when all alternative treatments have been exhausted or are unavailable and the conditions specified below have been fulfilled. FDA and CryoLife agree that only the following human allograft tissues will be distributed for the specified medically urgent uses when alternative therapies are exhausted or unavailable:

- Non-valved cardiac conduits and patches procured from the ascending aorta and pulmonary trunk and branch for use in neonates and pediatric patients.

- Saphenous veins used for peripheral vascular bypass when no alternative materials are available.

- Femoral veins and arteries used for dialysis access when synthetic access device becomes infected and when external bridging is not possible.

- Aorto-iliac artery for infected abdominal grafts:

- femoral veins and arteries for iliac extension.

- Saphenous veins used for cardiac bypass when no suitable autologous tissue is available, including internal mammary, saphenous and other sites.

CryoLife and FDA agree that the specified tissues will be released for distribution only after CryoLife completes the following steps:

1. CryoLife will obtain a prescription from the surgeon for the tissue requested, including its specific use. The prescription will include the surgeon's tissue requirements for the patient. CryoLife will obtain from the surgeon a written certification that all other alternatives have been exhausted or are unavailable and that there is an urgent medical need for the tissue requested. For non-valved cardiac conduits and patches, CryoLife will obtain from each pediatric surgical center, in addition to the information described above, a request for the number of tissues that the center estimates it may use during the 45 day period for which this agreement is in effect.

2. CryoLife will inform surgeons that patients should be notified that the tissue is subject to an FDA recall, that there is a risk of infection associated with these tissue implants, and that alternative approaches, including non-surgical, should be exhausted or unavailable before using this tissue. CryoLife will obtain from the surgeon either a written acknowledgement that he has or will inform the patient of the above factors or, if this is contained in the informed consent, a copy of that document. CryoLife will also request immediate feedback from surgeons of any suspected infections after use of the tissue.

3. CryoLife will contact Tissue and Organ Procurement Organizations (TOPOs or OPOs) or other facilities that procured the tissues described above to ascertain if microbial cultures were performed during or after procurement; if cultures were performed, CryoLife will obtain documentation of the results of that testing. Any tissues shown by these tests to have been obtained from a donor whose tissue has cultured positive for microorganisms that have been associated with infection, or could be indicative of other

microorganisms that have been associated with infections, including but not limited to, Clostridium, Candida and Escherichia coli (hereafter referred to as indicator organisms), will not be released. If there are no microbial records available from the procurement site, CryoLife will include additional labeling as described in paragraph number 6 below.

4. CryoLife will perform a retrospective review of its own pre-packaging microbiological testing records for all associated donor tissue. If indicator microorganisms were isolated, the tissue will not be released.

5. CryoLife will perform a search of its complaint files to ascertain if there are any complaints regarding infections for all associated donor tissue. If there are any such complaints with regard to any associated donor tissue, no tissue from the same donor will be released.

6. CryoLife will provide the following information in addition to its routine labeling for tissue for distribution: in bold, red caps, in at least 12-point, " BIOHAZARD: THIS TISSUE IS SUBJECT TO AN FDA ORDER FOR RECALL AND RETENTION BASED ON FDA CONCERNS OVER THE VALIDATION OF THE METHODS USED TO PREVENT INFECTIOUS DISEASE CONTAMINATION AND CROSS-CONTAMINATION. IT IS BEING RELEASED DUE TO URGENT MEDICAL NEED AND IS ONLY FOR USE FOR THE INTENDED RECIPIENT."

   For tissue not tested at procurement, CryoLife will further label the tissue as, "PROCUREMENT CULTURES WERE NOT PERFORMED PRIOR TO RECEIPT AND PROCESSING BY CRYOLIFE."

7. CryoLife will document and maintain records of its actions under this agreement, and make such records available for FDA review. For non-valved cardiac conduits and patches, CryoLife will also track and document all tissue that is released pursuant to this agreement.

In addition, CryoLife agrees to implement the following interim procedures to help prevent infectious disease contamination or cross-contamination of tissue during processing:

1. CryoLife will perform pre-processing cultures on all incoming tissues prior to antibiotics, disinfectants, or sterilizing agents that would include either 100% swabbing or 10% destructive testing. All testing of pre-processing samples will be performed by a contract laboratory with validated methods, until such time as CryoLife's test methods are adequately validated. Tissues contaminated with indicator microorganisms that cannot be reliably cleared by CryoLife's processing system will be discarded.

2. CryoLife will perform pre-packaging cultures on all tissue made available for distribution, using either 100% swabbing or 10% destructive sterility testing. All testing of pre-packaging samples will be performed by a contract laboratory with validated methods, until such time as CryoLife's test methods are adequately validated. All tissue from a donor will be discarded if indicator microorganisms are found in any tissue from that donor. In lieu of 100% swabbing or 10% destructive sterility testing, CryoLife will demonstrate that the current practice of processing companion tissue for the purpose of pre-packaging cultures adequately represents the tissue being processed through validation of this process.

3. CryoLife will establish a corrective action plan within 30 days that will include steps to validate its processing procedures to prevent infectious disease contamination and cross-contamination of tissue during processing, including any procedures to ensure that tissue distributed by CryoLife is free, or reasonably free, from microbial contamination. This corrective action plan will include specific and prompt timeframes for completion of each step. CryoLife agrees to engage a consultant/third party reviewer to assist CryoLife in this validation.

4. CryoLife agrees to replace tissue subject to the FDA Order and specified in this agreement with tissue that has been processed using the interim procedures above as soon as such tissue is available. As such newly processed tissue becomes available, CryoLife agrees not to release tissue subject to the Order and this agreement pending further arrangements for ensuring the proper disposition of such tissues. Any further arrangements must be agreed upon in writing between CryoLife and an authorized official

of the FDA.

This agreement will remain in effect for forty-five (45) working days from the date of signature by all parties. FDA will review records and other relevant information related to CryoLife's release of tissue under this agreement, as well as the status of CryoLife's corrective action plan, before determining whether this agreement should be renewed or modified to provide for any further release of tissue subject to the Order of Retention, Recall, and/or Destruction. FDA has encouraged CryoLife, and CryoLife has agreed, to implement adequate corrective actions as rapidly as possible and to replace tissue subject to the Order with tissue processed subsequently under the interim procedures. This agreement supplements the August 13, 2002, FDA Order for Retention, Recall, and/or Destruction and, except to the limited extent provided herein, does not in any way supercede, limit, or modify that Order.

/s/ Barbara A. Wood — 9/5/02

Barbara A. Wood — Date
Acting Director
Atlanta District Office

/s/ Steven G. Andersen — 9/5/02

Steven G. Anderson — Date
President and CEO CryoLife, Inc.

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EXHIBIT 99.1

FOR IMMEDIATE RELEASE

CONTACTS:
D. ASHLEY LEE
VICE PRESIDENT, CHIEF FINANCIAL OFFICER
(800) 438-8285

JOHN DEAVER
SENIOR VICE PRESIDENT, FLEISHMAN HILLARD
(404) 739-0111

CRYOLIFE REACHES AGREEMENT WITH FDA TO RESUME LIMITED TISSUE PROCESSING AND DISTRIBUTION

ATLANTA...September 6, 2002 CryoLife Inc. (NYSE: CRY), a tissue processing and medical device company, reached an agreement with the U. S. Food and Drug Administration permitting the company to immediately resume processing and limited distribution of its life-saving and limb-saving non-valved cardiac and vascular tissues.

The agreement allows CryoLife to distribute existing and newly processed non-valved cardiac conduits and patches, saphenous veins, femoral veins and arteries, and aorto-iliac arteries for specified medically urgent uses when alternative treatments have been exhausted or are unavailable. The Company estimates that most of the covered tissue under its control is used by surgeons under the conditions permitted by the agreement.

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"We remain confident in the safety of our processed tissues and continue to cooperate fully with the FDA," said CryoLife CEO Steve Anderson. "In many cases, our processed tissues offer treatments for conditions that could not be otherwise treated, such as certain repairs to a child's diseased heart," he added.

Since 1984, more than 90,000 CryoLife preserved allograft tissues have been implanted. The overall infection rates in surgeries involving CryoLife tissues are comparable to or below published infection rates in surgeries involving sterile synthetic implant devices.

"I applaud the fact that CryoLife tissues are once again available, as these tissues, which are often in short supply, are essential to modern medical care, especially for infants and small children," said John Lamberti, M.D., Director, Pediatric Cardiac Surgery, New York Weill Cornell Medical Center. "I have been implanting these valves and tissues for more than 15 years without incidence of infection."

"This is good news for patients to have the nation's largest tissue processor once again able to handle what is surely the most precious gift one human can give to another," said John Lee, Executive Director Tissue Services of DCI Donor Services.

The agreement allows the tissue to be released for distribution after CryoLife completes steps to assure that the tissue is used for approved purposes and that patients will be notified of risks associated with tissue use. Specifically, CryoLife must obtain physician prescriptions, and tissue packaging must contain appropriate warning labels. The agreement also calls for CryoLife to undertake to identify third-party records of donor tissue testing, and to destroy tissue from donors in whom micro-organisms associated with an infection are found.

In addition, the agreement, which has a forty-five working-day term, specifies interim operating procedures to permit CryoLife to distribute tissues processed during the term of the agreement. CryoLife also agreed to establish a corrective action plan within 30 days with steps to validate processing procedures. A copy of the agreement is available as an Exhibit to the Company's Form 8-K filed September 6, 2002, and on the Company's Web site, www.cryolife.com.

Forward-Looking Statements. Statements made in this press release that look forward in time or that express management's beliefs, expectations or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These future events may not occur as and when expected, if at all, and, together with the Company business, are subject to various risks and uncertainties. Such risks and uncertainties include the risk that the interim procedures will prove insufficient, that CryoLife may not be able to establish a satisfactory corrective plan within 30 days, CryoLife's dependence on cryopreservation of human tissue, the possibility that anticipated decreases in the Company's revenues and working capital may be severe, the possibility that SynerGraft-treated heart valves will not have the expected long-term functionality, repopulate with human recipient cells or reduce immune response, that future clinical SynerGraft or BioGlue test results will prove less encouraging than current results, the possibility that the SEC investigation could be concluded in a manner adverse to the Company, that SynerGraft, BioGlue, or other regulatory submissions will not be ready when planned or that anticipated regulatory approvals will not be obtained when expected, if at all, that surgeons will not continue to accept and use tissues preserved by the Company or its other products such as BioGlue, competition from other wound closure products, that CryoLife will be unable to find an investor in its proprietary light activated drug delivery systems or that such systems will prove ineffective in oncology applications, that pending government and legal proceedings against CryoLife will not be resolved in its favor, that the FDA may require the recall of heart valve tissue processed by CryoLife, that CryoLife may be forced to discontinue its tissue processing business due to the FDA Order or subsequent FDA actions, the possibility of rapid technological change, uncertainties regarding products in development, uncertainties related to patents and protection of proprietary technology, changes in economic cycles, competition from other companies, changes in laws and governmental regulations applicable to CryoLife and other risk factors detailed in CryoLife's Securities and Exchange Commission filings, including CryoLife's Form 10-Q Filing for the quarter ended June 30, 2002, and the Company's other SEC filings.

For additional information about the company, visit CryoLife's web site:

http://www.cryolife.com

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