DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street, N.E. Atlanta, GA 30309	2-3-14/03
	FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Connie J. Jones, Senior Director RA/QA

FIRM NAME	STREET ADDRESS
CryoLife	1655 Roberts Blvd., NW
CITY, STATE AND ZIP CODE Kennesaw, GA 30144	TYPE OF ESTABLISHMENT INSPECTED Human Tissue Processor/Medical Device Manu

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

1.

A). The firm did **not** retrieve allografts that are known to be associated with infections (processed **prior** to the FDA Recall Order – 8/12/02) from the market. At least twelve distributed allografts are associated with reported Clostridium, Candida, or E. Coli infections. No actions had been taken by the firm at the initiation of the current inspection (2/5/03). Corrected not Verified 2/14/03 CDB

B). The firm reportedly conducted a review (look back) of all allografts processed between 1998-2002. There was no established plan, procedures or corrective action request (CAR) detailing this review. Corrected: verified 2/14/03 CDB

2. The complaint handling system is deficient in that:

A). The firm did not document and/or follow-up on a complaint received on 1/2/03 from the agency through Medwatch [redacted] for allograft [redacted] The heart valve is reported to have been infected with Aspergillus 2 years ago and most recently with Staphylococcus. The complaint was not investigated and, the firm did not file an MDR upon notification of the incident. Corrected not verified 2/14/03 CDB

B). Many complaints are incomplete and/or the files are disorganized. For example,

1. The firm did not have complete follow-up for complaint (#02-5210367). The complaint (reported to Cryolife on 9/10/02) indicated that a femoral vein was implanted 5/24/02 and the patient developed an infection not normally acquired through other exposures. The complaint reported "heavy growth of Corynebacterium. Heavy growth mixed anerobes including prevotella species". No complaint summary and limited follow-up reports were available in the complaint file when requested on 2/5/03. The complaint was still outstanding. Corrected: verified 2/14/03 CDB

2. As of 2/10/03 the firm has at least 20 incomplete complaint investigations as that have been **outstanding** for 174-255 days. Under Consideration 2/14/02

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Claudette D Brooks Karen A. Coleman Mary Alice Papdimitriou Paul A. Bonneau	Claudette D. Brooks, CSO Karen A. Coleman, CSO Mary Alice Papdimitriou, CSO Paul A. Bonneau, Microbiologist	2/14/03

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60 Eighth Street, NE Atlanta, GA 30309	2/3-
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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

3. Complaints#02-5210373, #02-5210372, #02-5210326 have been assigned however, specifics about these complaints have not been documented. Corrections promised 2/21/02

4. As of 1/31/03, the firm's complaint files contained 72 "open" complaints. The complaints have been in open status 144 days (4.5 months) or longer. The complaint investigations have not been reviewed and final dispositions have not been determined. Under Consideration 2/14/03

C. The firm's QA unit does not have oversight for complaint handling and does not review the complaints, complaint investigations or complaint corrective actions/follow-up. Corrected not verified

3. The firm's bacteriostasis/fungistasis testing on the anti-microbial cocktail for [redacted] failed to establish consistent hold times across all challenge organisms and anti-microbial solutions. Under Consideration

4. The firm's bioburden program is deficient in that:

A. The firm has not completed the validation protocol ~~and methods~~ development design CDB 2/14/03 to address incoming bioburden as outlined in the corrective action plan.

B. As of 2/11/03 the firm has not ~~analyzed~~ trended CDB 2/14/03 the cumulated bioburden data from [redacted] which began in June 2002.

5. The firm does not perform an assessment into the root cause when donor [redacted] showing different organisms.
For example:

Donor ID	Pre-Culture Results	Post-Culture Results
[redacted]	Streptococcus pyogenes	Propionbactrium acnes
	Enterobacter aerogenes	Propionbactrium acnes
	Negative	Staphylococcus epidermidis
	Pseudomonas fluorscens	Pseudomonas aeruginosa

Item Under Consideration 2/14/03 CDB

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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60 Eighth Street, NE Atlanta, GA 30309	2/3-
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO:

FIRM NAME	STREET ADDRESS
CryoLife	1655 Roberts Blvd.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Kennesaw, GA 30144	Human Tissue Processor/Medical Device Manuf

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:
For example:

6. The firm has not performed the following equipment qualification:

A. The three [redacted] being used on human tissue (E0113F, E0113J, E0113G) did not have complete validation; the Performance Qualifications were not done. Corrected not verified 2/14/03 CDB

B. Current Preventative Maintenance procedures for the [redacted] are not in accordance with the manufacturer's recommendations. Corrected not verified 2/14/03 CDB

7. On 2/3/03 an area of rust/corrosion was observed along the bottom back panel of Laminar flow hood (E00491) located in the Microbiology Lab. corrected not verified 2/14/03 CDB

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