



WARNING LETTER

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January 20, 1998

Mr. Jeffrey A. Thomas, Executive Director
Doheny Eye and Tissue Transplant Bank
1450 San Pablo Street, Suite 3600
Los Angeles, CA 90033

WL13-8

Dear Mr. Thomas:

During an inspection of the Eye and Tissue Transplant Bank, conducted on 11/10/97 through 12/16/97, our investigators documented violations of Section 361 of the Public Health Service Act and Title 21, Code of Federal Regulations (CFR), Part 1270 as follows:

1. Failure to determine that a donor of banked human tissue intended for transplantation is suitable, and failure to follow written procedures for all significant steps for determining the suitability of banked human tissue intended for transplantation [21 CFR 1270.5 and 1270.7 (b)]. For example:

There were at least fifty-five instances where the firm failed to follow their Standard Operating Procedure (SOP), by not recalling and/or assuring the destruction of distributed tissues which were not suitable for transplantation due to a) repeatedly reactive viral markers and/or b) risk factors revealed in medical/social history, clinical and/or physical evidence.

2. Failure to assure all banked human tissue is quarantined [21 CFR 1270.9 (b)] until:
(1) All infectious disease testing has been completed, reviewed by a responsible official, and found to be negative and (2) Donor screening has been completed, reviewed by a responsible official, and determined to assure freedom from risk factors for or clinical evidence of hepatitis B, hepatitis C, or HIV infection. For example:

There was no documentation to show donor suitability information was being reviewed upon notification of any issues relative to the safety of the donor tissues as required by the firm's SOP.

The firm failed to prevent the distribution of banked human tissue for transplantation from donors who were determined to be unsuitable.

3. Failure to assure that there is not hemodilution sufficient to alter test results [21 CFR 1270.5 (d) (2)]. For example:

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There were instances where hemodilution worksheets were found to be inaccurate and/or incomplete.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in full compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes Order for Retention, Recall and/or Destruction, and/or Injunction.

Furthermore, at the conclusion of the inspection you agreed to review and audit for suitability corneal tissue procured under California Legislative Consent between January 1995 to December 1997. This review and audit was to include, but is not limited to, obtaining and evaluating medical examiner/coroner's reports, autopsy reports or police records, and if necessary, additional information from the donor's next of kin. Moreover, upon determination that any tissue was found to be unsuitable for transplantation you agreed to promptly retain, recall and/or notify the transplanting physician of the adverse findings.

Because of the seriousness of these violations and the fact your firm was issued an FDA Order for Retention, Recall, and/or Destruction on October 20, 1994, please arrange to meet with the District Office staff within 15 working days of receipt of this letter. At this meeting, please be prepared to discuss and present in writing the specific steps you have taken to correct these violations, prevent their recurrence and the steps you plan to implement to assure continued compliance. In addition, please include your findings of the audit conducted on the corneas and the corrective action taken to remedy the situation.

If you feel you cannot meet the above time frames, please notify the district contact below with the reason for the delay and the time within which the corrections will be completed. Finally, we acknowledge the receipt of your response to the FDA-483 on 1/16/98, and the response is under review.

The Los Angeles District contact is Robert W. Nicol, Compliance Officer who can be reached at (714)798-7668.

Sincerely yours,



Elaine C. Messa
District Director, Los Angeles
U. S. Food and Drug Administration