



HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

m437n

Refer to: CFN 1125034 / FEI 3001236466

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

August 25, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Frederick G. Caudle
Chief Executive Officer
Lions of District 22-C
Eye and Tissue Bank and Research Foundation, Inc.
9470 Annapolis Road, Suite 415
Seabrook, Maryland 20706

Dear Dr. Caudle:

During a Food and Drug Administration (FDA) inspection of your tissue bank located in Seabrook, Maryland, conducted June 27 through July 21, 2000, our investigator documented violations of Section 361 of the Public Health Service Act and Title 21, Code of Federal Regulations (21 CFR), Part 1270, as follows:

Failure to accurately document quarantine of corneas coded as being suitable for surgical transplantation prior to and during distribution, as required by 1270.35 (c). For example, corneas coded as being for surgical implant were shipped to [REDACTED] prior to the receipt of serological testing showing they were repeat reactive HIV-I/II. There was no documentation to show that they had been identified as being quarantined or that the corneas had not yet been determined to be suitable for implant, as required by 1270.33 (c).

Failure to maintain accurate, indelible, and legible records of each significant step in the identification, testing, and disposition of tissue for human transplantation, as required by 1270.33(a), in that records had been altered with no explanation, whiteout was used in the records obscuring the original information, records conflicted with one another and lacked dates and signatures to show review by responsible individuals.

Failure to follow written procedures as required by 1270.31. For example, corneas identified as being distributed for research purposes were not documented in the "Research Tissue Requests" or Practice Logs as required by your procedures.

The above violations 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 compliance with all requirements of the federal regulations.

Dr. Frederick G. Caudle
Page 2
August 25, 2000

We acknowledge receipt of your FDA-483 response letter, received August 24, 2000. Your response, however, does not provide sufficient detail of exactly what corrections are being made or how they are to be accomplished. Without this information, we can not adequately assess your corrections.

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such actions include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,

A handwritten signature in black ink, appearing to read 'LB', with a stylized flourish extending to the right.

Lee Bowers
Director, Baltimore District