

VIA FEDERAL EXPRESSFood and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751WARNING LETTER

FLA-02-12

November 6, 2001

David C. Brown, M.D.
Founder and Owner
Eye Centers of Florida
4101 Evans Avenue
Ft. Myers, Florida 33901

Dear Dr. Brown:

During an inspection of your Southwest Florida Eye Bank, located at 4140 Evans Avenue, Suite 100, Ft. Myers, Florida, on July 24-26, 2001, our investigator, Joan S. Norton, documented serious violations of Section 361 of the Public Health Service Act (PHS Act) and Title 21, Code of Federal Regulations, Part 1270 (21 CFR 1270) as follows:

Failure to accurately document the results and interpretation of all required infectious disease tests of cornea donors prior to distribution and transplantation [21 CFR 1270.21(d)]. For example, no viral marker test results were available for donor [REDACTED]. Two corneas from this donor were approved for transplantation on April 10, 2000 and one cornea each was implanted in two different patients on April 11, 2000. In addition, corneas from donor [REDACTED] were approved for distribution and transplantation on February 1, 2000 prior to receiving viral marker test results. One of these corneas was transplanted and one was discarded.

Failure to ensure that donor specimens are tested using a FDA licensed donor-screening test in accordance with manufacturer's instructions [21 CFR 1270.21(a)]. For example, viral marker test specimens for donor [REDACTED] were not tested using a FDA licensed screening test kit approved for testing cadaveric samples. Eye bank personnel did not know which test kits your contract laboratory was using for viral marker testing and could provide no documentation or assurance the laboratory was conducting viral marker testing appropriately.

Failure to adequately determine donor suitability prior to release and distribution of corneas for transplantation [21 CFR 1270.21(f)]. For example, no documentation was available to show that the medical director reviewed the medical and social history, viral marker test results and other pertinent

information for donor ██████████ to determine suitability prior to release of corneas for transplantation. The right cornea from this donor was transplanted into a patient on November 14, 2000. In addition, review of ██████████ donor record files revealed that all were missing information on donor medical and social histories regarding high risk factors for and clinical evidence of HIV and Hepatitis infections. At least four of these files contained no documentation to show that relevant medical and social behavior histories were obtained from a next-of-kin or other knowledgeable person. The donor record currently in use limits the physical assessment of donors to stature and skin integrity. No documentation is available to show a physical examination of donors that includes clinical signs of sexually transmitted disease, signs of IV drug use or other high-risk behavior.

Failure to prepare and follow adequate written procedures for all significant steps used in determining donor suitability, quarantine of tissue and viral marker testing [21 CFR 1270.31(b)]. Your written procedure for obtaining medical and social histories for screening donors is inadequate in that the procedure fails to include all significant steps for conducting interviews of individuals who have knowledge of the donor, for example, next-of-kin, life partner or attending physician. Your written procedure for quarantine of tissue is inadequate in that release is based on viral marker test results only and does not include completion of donor screening and review by a responsible person prior to the approval of the tissue for transplantation.

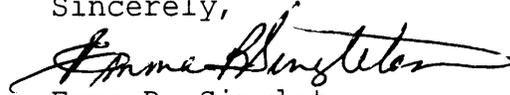
The above violations are not intended to be an all-inclusive list of deficiencies at your eye bank facility. It is your responsibility to ensure that all ocular tissues procured, processed and distributed by your eye bank are in compliance with the PHS Act and all requirements of 21 CFR 1270.

You should take prompt action to correct these violations. Failure to correct these violations may result in further administrative and/or regulatory action being taken by FDA without further notice. Such action includes a FDA Order for Retention, recall and destruction, seizure and/or injunction.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their recurrence. Your response should include examples of documentation showing that corrections have been achieved. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time period within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

A handwritten signature in cursive script, appearing to read "Emma R. Singleton". The signature is written in black ink and is positioned above the printed name.

Emma R. Singleton
Director, Florida District