



GEORGIA EYE BANK, INC.

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May 7, 2001

Jane E. Henney, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 97N-484P: Current Good Tissue Practice for Manufactures of Human Cellular and Tissue-Based Products; Inspection and Enforcement; Proposed Rule; 21 Federal Register Part 1271; January 8, 2001

Dear Dr. Henney:

Georgia Eye Bank, Inc., an IRS designated 501(c)(3) nonprofit organization, is dedicated to being a leader in eye banking. Since its founding in 1961, Georgia Eye Bank (GEB) has helped to restore the sight of more than 23,000 people through corneal transplantation. Approximately 1,000 corneal transplants are performed each year in Georgia with tissue provided by GEB.

The estimated cost to Georgia Eye Bank of implementing FDA Good Tissue Practices is between \$90,000 and \$100,000. Our current budget is approximately \$2,000,000. Implementation will increase our budget by roughly 5%, resulting in the need to increase our processing fee by \$90-\$100 for each cornea provided for transplant.

We are governed by a Board of Trustees, which employs the President/CEO, who governs the day-to-day operation of the Eye Bank. Georgia Eye Bank also has two renowned ophthalmologists serving as Co-Medical Directors and a Medical Advisory Committee to advise the President/CEO on any medical matters.

GEB's work is performed under the guidelines set forth by the medical and ethical standards established by the Eye Bank Association of America, while facilitating the hospital's compliance with state and federal laws/regulations. One of the primary

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objectives of our relationship with each hospital is to support a system for potential donor referrals. The Eye Bank's responsive service team starts with healthcare professionals, who work in collaboration with GEB staff members to ensure that the option for eye donation is presented in a sensitive and caring manner. Screening, which includes obtaining necessary medical information, and evaluation of eye tissue ultimately determine the suitability of tissue for transplantation.

Should you require any further information, please give me a call at (404) 504-2580.

Sincerely,

Bruce H. Varnum

Bruce H. Varnum
Chair, Board of Trustees
President/CEO