



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

November 5 , 1998

WARNING LETTER

Ref: 99-DAL-WL-02

**VIA FACSIMILE AND
FEDERAL EXPRESS**

Mr. Paul Anderson
Chairman
Southwest Tissue Services
One Riverwalk Place
700 N. St. Mary's, Suite 1215
San Antonio, Texas 78205-3501

Dear Mr. Anderson:

A Food and Drug Administration (FDA) inspection of Southwest Tissue Services, San Antonio, Texas, was conducted on August 26-28 , 1998. FDA review of the information and records collected during that inspection, and subsequent investigations revealed significant deviations from Title 21, Code of Federal Regulations, Part 1270 (21 CFR 1270), Interim Rule, as follows:

Tissue from donors which tested repeatedly reactive for HIV and HbsAg by EIA was distributed for transplantation [21 CFR 1270.5(c)]¹ , as follows:

Donor No. 15495- HIV

Donor No. 11695, 18395, 19595, 94001, 15297, 10797- HbsAg

The investigator presented a list of observations (FDA-483) to you and your staff at the close of the inspection and a copy is being enclosed with this letter for your reference. 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.

¹ This deviation would also be a violation of the Final Rule, 21 CFR 1270.21(d).

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You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. We acknowledge your recall efforts and management changes you have instituted, as an effort to prevent future occurrences of these types of violations. **Additionally, we note you have stated you will perform an audit of all viral marker testing records, including those viral marker testing records of firms who conducted infectious disease testing for your establishment, to determine whether any additional human banked tissue for transplantation was unsuitable for distribution.**

Please notify this office in writing, within fifteen (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, including the status of the audit and any other related information. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please address your response to Gwen Gilbreath, Compliance Officer, at the above letterhead address.

Sincerely,



^{fol} Joseph R. Baca
District Director

JRB/GSG

Enclosure

cc: Dr. Manuel M. Quinones
Medical Director

Mr. Don Scott
Interim Executive Director