



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94832d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-04-36

June 18, 2004

Lawrence A. Hopkins
President and CEO
Southeast Tissue Alliance, Inc.
6241 N.W. 23rd Street, Suite 400
Gainesville, Florida 32653

Dear Mr. Hopkins:

During an inspection of your human tissue recovery firm, located at the above address, between March 29 and April 1, 2004, our Investigator, Holly M. Scott, documented significant deviations from the regulations for human tissue intended for transplantation set forth in Title 21, Code of Federal Regulations, Part 1270 (21 CFR 1270), promulgated under the authority of Section 361 of the Public Health Service Act (PHS Act), 42 U.S.C. § 264. The observed deviations include the following:

1. Failure to make a determination by a responsible person that a donor of human tissue intended for transplantation is suitable, including ascertainment of the donor's identity, as required by 21 CFR 1270.21 (f) in that on June 13, 2002, two of your recovery specialists in Melbourne (Palm Bay), Florida, failed to properly identify donor [REDACTED] and obtained tissue from another cadaver. You subsequently released and distributed tissue from that cadaver without properly identifying the donor. This resulted in the recovery and distribution of unsuitable human tissues from a cadaver for whom donor suitability had not been determined.
2. Failure to maintain records documenting the destruction or other disposition of human tissue, as required by 21 CFR 1270.35(d). Specifically, there is no documentation to show the destruction of tissue products recovered from the incorrect cadaver (identified as coming from donor [REDACTED] but actually obtained from another cadaver) on June 13, 2002, which included Femur, TibFibEnbloc, Hemi Pelvis, Achilles Tendon and Fascia Lata.
3. Failure to follow written procedures for all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor, as required by 21 CFR 1270.31(b).

a. Your SOP "Donor Identification & Consent Verification", Document Number 20-009, Revision 003, Effective Date 11-08-02, Section 8.04 requires recovery technicians "on all cases to call the Care Center and confirm ID, relay the donor ID information and verify the consented tissues with the Care Center coordinator." On March 14, 2003, a second incident occurred where two of your recovery specialists in Jacksonville, Florida, failed to properly identify donor [REDACTED]. Through your own investigation you determined that neither recovery technician confirmed the identity of the donor. This resulted in the recovery of human tissues from a cadaver who was not donor [REDACTED] and for whom donor suitability had not been determined. These tissues were not distributed. The recovery specialists subsequently detected their donor identification error and the recovered tissues were returned to the cadaver.

b. A review and comparison of 47 donor charts and recorded consents revealed the following:

(1) On March 31, 2002 (donor [REDACTED], donor screening employee (B) failed to completely read approximately 12 donor suitability questions in their entirety to the next-of-kin (NOK), which caused the loss of pertinent medical information.

(2) On January 14, 2004 (donor [REDACTED], donor screening employee (B) again failed to read approximately twenty-five donor suitability questions to the NOK in their entirety, leaving out pertinent medical questions. On at least one occasion, this same screening employee changed medical history question 13d from "Has (he/she) donor name had sex in the past 12 months with any person known or suspected to have Hepatitis B or C, or infected with HIV." The employee asked the NOK "Was donor name suspected to have Hepatitis C."

We acknowledge receipt of your April 13, 2004 letter submitted in response to the observations listed on the FDA 483 issued to your firm at the close of our inspection. We consider most of the corrective actions stated in your response to be inadequate for the following reasons:

- Response #1 - After the improper identification of donor [REDACTED] on June 13, 2002, the mandatory step referred to was added to a November 8, 2002, revision of your SOP 30-011. This was approximately four months prior to the second occurrence of improper donor identification. Your recovery employees have been required to phone in the donor identity since November 8, 2002. You have not established an adequate method to verify the identity of donors in the field or to confirm that recovery employees have properly verified the identity of the donor. During the second

occurrence, your recovery employees followed this procedure and phoned in the identity of the donor, which was incorrect. You may want to consider implementing a method such as taking a digital photograph of the donor toe-tag for submission with the recovery record to fully establish and verify the identity of donor cadavers.

- Response #2a - The referenced communication log provided states there was an error in positively identifying the donor, but the corrective action report does not document that the tissues recovered from the improperly identified donor were destroyed.

- Response #2b - You state that "SOP 60-002 QA review of Donor Records, section 8.06 has been revised to require certain documentation". However, a copy of this revised SOP was not provided with your response for review and evaluation.

- Response #3 - This response is inaccurate. The observation refers to the first misidentified donor whose recovered tissues were in fact distributed in June 2002. Tissues from this donor were not returned to the cadaver as stated in your response. It was the second misidentified donor whose recovered tissues were placed back into the body.

- Response #4a - The communication log references the corrective action CAR 02-016 as stated. However, the corrective action does not reference or fully document that the tissues were destroyed. It references only a "description of condition," which is "failure to positively identify the donor."

- Response #4b - This response appears adequate.

- Response #5 - This response does not show that a corrective action report was created for observations #5 a, b, or c, and no corrective action reports were provided with your response for review. Your response states that your processors were notified to place only those tissues that have not been processed under quarantine, but fails to address tissues that may have been processed and distributed. No inventory of these tissues or destruction information was provided.

- Response #6 - The new autoclave log form appears more user friendly and should be easier for the technician to complete. However, we believe you may be incorrect in your assumption that these errors have been eliminated. Three of the five referenced occurrences happened after the new form was implemented. For example, for donor [REDACTED] the autoclave logs state that tissue set #1 was sterilized, but the donor chart states that tissue set #2 was used in recovery. No documentation was provided to show that tissue set #2 was in fact sterilized.

We also acknowledge receipt of your April 26, 2004, letter providing additional information regarding the FDA 483 observations 3, 4, and 5. We consider this response to be inadequate as well for the following reasons:

- Observation 3 - Destruction records are required by regulation [21 CFR 1270.35(d)] and should have been maintained by your firm since the beginning of operations. Your notification to tissue processors that destruction records will now be required appears adequate. However, no commitment is made in your response to fully audit your records for previous donors and obtain destruction records if necessary.

- Observation 5 - You are improperly basing this corrective action on a "promise" by employees to follow the established SOP's, rather than implementation of a method, program, or procedure to ensure that employees follow established SOPs.

- Observation 5c - Your response fails to address numerous other medical/social history questionnaires that the responsible employee has taken over the last two years. We understand you have initiated a recall on tissue products from only one donor who was inadequately screened by this employee and you have not determined whether other unsuitable tissues may have been distributed as a result of this employee's poor performance.

The above identification of deviations is not intended to be an all-inclusive list of deficiencies at your human tissue recovery facility. As President and CEO, it is your responsibility to ensure that all human tissues procured and distributed by your facility are in compliance with Section 361 of the PHS Act and all requirements of 21 CFR 1270.

You should take prompt action to correct these violations. Failure to correct these deviations may result in further regulatory action being taken by FDA without further notice. Such action includes an FDA Order for Retention, Recall and/or Destruction of Human Tissue.

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 deviations, 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,

Elizabeth W. Diamond

for
Emma R. Singleton
Director, Florida District