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Food and Drug Administration  
Baltimore District Office  
Central Region  
600 North Drive, Suite 101  
Baltimore, MD 21215  
Telephone: (410) 779-5454  
FAX: (410) 779-5707

03-BLT-08

January 13, 2003

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Marion F. Borowiecki  
Chief Executive Officer  
Transplant Resource Center of Maryland, Inc.  
1540 Caton Center Drive, Suite R  
Baltimore, Maryland 21227

Dear Mr. Borowiecki:

The Food and Drug Administration inspected your tissue bank establishment located at 1540 Caton Center Drive, Baltimore, Maryland on August 30, September 3-6, 9, and 12, 2002. The inspection found significant violations of the regulations for human tissues 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 (PHS) Act.

The violations of concern to us are as follows:

1. TRC failed to accompany quarantined human tissue with records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation. The FDA inspection documented that TRC routinely shipped quarantined tissue to one consignee without records to indicate that the tissue had not been determined to be suitable for transplantation. The FDA inspection also documented that three of [REDACTED] lots of donor tissue were shipped to a processing establishment without such records. [21 CFR 1270.33(c)]. The importance of including such records with donor tissue was underscored when the donor tissue that did not have such accompanying records subsequently tested positive for infectious diseases.
2. TRC failed to prepare and follow written procedures for designating and identifying quarantined tissue [21 CFR 1270.31(c)], in that:
  - a. TRC's written procedures entitled "[REDACTED]" and "[REDACTED]" do not define how

donor tissue is designated and identified from the time of recovery until the time that infectious disease testing results are determined.

- b. TRC has no procedures for labeling and shipping quarantined tissue that has not been determined to be suitable for transplantation prior to shipment.
  - c. TRC has no written procedures for assessing the suitability of donor tissue with discordant serology test results including, but not limited to, review and approval by the medical director.
3. TRC failed to prepare, validate, and follow written procedures for the prevention of infectious disease contamination and cross-contamination during processing of skin. [21 CFR 1270.31(d)] For example, TRC failed to validate its cleaning procedure entitled "[REDACTED]" and failed to prepare, validate, and follow any other written procedure to prevent contamination or cross-contamination during tissue processing. The website listed below contains general information to aid in developing and validating such procedures.
  4. TRC shipped human skin tissue intended for transplantation without a summary of records or copies of the original records of the donor's relevant medical records as defined in 21 CFR 1270.3(t). [21 CFR 1270.21(e)]

The above deficiencies are not intended to be an all-inclusive list of deficiencies at your tissue bank establishment. The noted deficiencies may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. It is your responsibility to ensure that all donor tissue recovered, processed, and distributed by your tissue bank establishment is in compliance with all applicable requirements of 21 CFR Part 1270 and the PHS Act. You may obtain general information on current FDA regulations and guidance concerning human tissue for transplantation at <http://www.fda.gov/cber/tiss.htm>.

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

We acknowledge receipt of your letter dated September 24, 2002, responding to the FDA inspection of your establishment on August 30, September 3-6, 9, and 12, 2002. We have completed our review and have the following comments.

Observation 1: In its response, TRC proposed to implement corrective action by October 31, 2002. Please provide the status of TRC's implementation of the promised corrections.

Observation 2: Your response to observation 2 is inadequate. The written procedure, "[REDACTED]" which is attached to your response, fails to address additional controls necessary to prevent inadvertent release of unsuitable tissue. For example, it fails to describe processes or procedures for record keeping when discordant test results are received, and processes or protocols for the Medical Director to follow in making the final suitability decision. Additionally, the written procedure lacks clarity and detail.

Observation 3: Your response to observation 3 provides an acceptable timeframe within which to conduct and implement validation of the cleaning procedure. FDA will review TRC's progress in

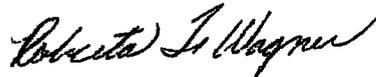
validating and following the cleaning procedure during the next inspection. However, your response does not address the general lack of procedures to prevent infectious disease contamination and cross-contamination of tissue during processing.

Observation 4: TRC's response to observation 4 proposed a reasonable corrective action. Please provide information on the status of TRC's proposed corrective action.

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 documentation that corrections have been achieved. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Vinetta Howard-King, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21228. If you have any questions, please do not hesitate to contact Ms. Howard-King at (410) 779-5454, extension 413.

Sincerely,



for

Lee Bowers  
Director, Baltimore District