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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

November 14, 2001

WARNING LETTER
2002-DT-10

Irvin D. Reid
President
Wayne State University
656 West Kirby
Detroit, Michigan 48202

Dear Mr. Reid:

The Food and Drug Administration (FDA) conducted an inspection of the Detroit Receiving Hospital Burn Center's human tissue bank from September 19 through 26, 2001. During this inspection, our investigator documented significant violations of Section 361 of the Public Health Service Act and Title 21, Code of Federal Regulations, Parts 1270 (21 CFR 1270) and 1271 (21 CFR 1271), as follows:

- 1) Failure to make an adequate determination of donor suitability for human tissue intended for transplantation, as required by 21 CFR 1270.21. For example:
 - A) Human allograft skins from donors [REDACTED] and [REDACTED] were released for use despite the absence of records indicating that these donors' specimens had been tested and found negative, using FDA licensed screening tests, for HIV-1, HIV-2, hepatitis B, and hepatitis C.
 - B) Human allograft skin from donor [REDACTED] was released for use despite the absence of relevant donor medical records documenting freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C, and HIV infection.
 - C) Human allograft skin was released for use without a determination having been made by a responsible person that the donor was suitable. This includes ascertainment of the donor's identity and review of accurately recorded medical records which documents freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C and HIV infection.

- 2) Failure to have and to follow written procedures for all significant steps associated with obtaining, reviewing and assessing relevant medical records of donors of human tissue intended for transplantation, as required by 21 CFR 1270.31(b).
- 3) Failure to have and to follow written procedures for designating and identifying quarantined tissue, as required by 21 CFR 1270.31(c).
- 4) Failure to quarantine human tissues until donor screening has been completed, reviewed by a responsible person, and determined to assure freedom from risk factors for and clinical evidence of HIV infection, hepatitis B, and hepatitis C, as required by 21 CFR 1270.33(b)(2). For example,
 - A) Human allograft skin from the following donors was available for use despite the lack of adequate information to assure freedom from risk factors for and/or clinical evidence of HIV infection, hepatitis B, and hepatitis C: Donor [REDACTED] donor [REDACTED] donor [REDACTED] and donor [REDACTED]
 - B) Human allograft skin from donor [REDACTED] was available for use despite the absence of relevant donor medical records documenting freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C and HIV infection.
 - C) Donor records and summary donor records do not contain any indication that they have been reviewed by, and determined suitable for transplantation by, a responsible person designated to perform such reviews.
- 5) Failure to maintain records documenting that human tissue intended for transplantation has undergone appropriate infectious disease testing and screening, and that the records have been reviewed by the person responsible for such reviews, and that the tissues have been determined to be suitable for transplantation, as required by 21 CFR 1270.33(d).
- 6) Failure to adequately document the receipt, distribution and destruction or other disposition of human tissues, as required by 21 CFR 1270.35. For example, there is no documentation of the amount of tissue from each donor and the disposition of all such tissues.
- 7) Failure to register this establishment and to submit a list of all human cells, tissues, and cellular and tissue-based products that this establishment manufactures with the Food and Drug Administration, as required by 21 CFR 1271.21(a).

A copy of the List of Inspectional Observations (Form FDA 483) issued at the conclusion of the inspection is enclosed for your information and reference.

This letter is not intended to be an all-inclusive list of the deficiencies that may exist at your facility. It is your responsibility to ensure that your tissue bank is in compliance with all applicable federal regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. Some of the available enforcement actions are an Order for Retention, Recall and/or Destruction and/or injunction.

We acknowledge receipt on October 24, 2001 of Dr. Prasad's undated response to the List of Inspectional Observations. We have reviewed this response and consider it inadequate. Please note that the numbering system used for our comments corresponds to the observations as listed on the List of Inspectional Observations and in Dr. Prasad's response letter.

1. The "Date-to-Date Record of Allograft" data sheet is inadequate for its intended use, as the space provided (in the blocks) for recording the data is not large enough for the user to legibly document the required information. Also, we note that detailed procedures on how to complete the data sheet were not provided to us.
2. The response did not provide any documentation regarding donor [REDACTED] related to donor screening, donor physical or serology results.
3. The serology results for donors [REDACTED] and [REDACTED] are discrepant, in that different tests were reported for each donor.
- 4 - 6. The written protocols for quarantine, distribution, and disposition are inadequate in that they lack step-by-step instructions describing how each of these procedures is to be performed.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. 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 implemented.

Warning Letter 2002-DT-10
Wayne State University

November 14, 2001
Page 4

Your reply should be directed to Sandra Williams, Compliance Officer, at the above address.

Sincerely,


Joann M. Givens
District Director
Detroit District

Enclosure: FDA 483

