



September 18, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863**WARNING LETTER**
CHI-30-00**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Thomas Victor, MD, Chairman,
Department of Pathology and Laboratory Medicine
Evanston Hospital Blood Bank
2650 Ridge Avenue
Evanston, IL 60201

Dear Dr. Victor:

A Food and Drug Administration Investigator conducted an inspection of the Evanston Hospital Blood Bank from August 1 through 8, 2000. The inspection revealed deviations from Title 21, Code of Federal Regulations, Parts 606-680. These deviations cause the blood products prepared at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act). At the conclusion of the inspection, a Form FDA-483, List of Observations, was issued to and discussed with Dr. James Perkins, Director. A copy of the Form FDA 483 is enclosed. The deviations found include, but are not limited to, the following:

Failure to maintain adequate donor record files [CFR 606.160(b)]. For example, the investigator selected donor records contained in the donor deferral registry (DDR) maintained by your firm. When our investigator selected several donors at random by their social security numbers, one donor (donor [REDACTED]) did not have a deferral card in the DDR [REDACTED]. Donor [REDACTED] was positive for HTLV-I by both EIA and Western Blot Assays. Also, our investigator reviewed approximately twenty active BDR files for donors requiring deferral by history. The review of these records showed that there was no card in the DDR for donor [REDACTED], who was diagnosed with uterine cancer 2 years prior to presenting for donation. Section 5, page 5, of your blood bank SOP #700, "Donor Registration and Allogeneic Screening," requires that donors with a history of solid tumor cancers be deferred for at least 5 years.

Failure to follow certain Standard Operating Procedures (SOPs) [21 CFR 606.100(b)]. For example, SOP #700 requires that when a donor indicates that he or she donated previously under a different name, the old BDR must be located and attached to the file. The SOP also states that "if no old BDR is found, write the donor's previous name and document "BDR not found" or "Donation elsewhere." Our investigator reviewed the records of several donors, including donors [REDACTED], [REDACTED] and [REDACTED]. Each

of these three donors reported a name change in response to screening question #1. However, none of the BDRs for these three donors indicated that the files were searched to obtain the donors' old records. Also, none of the BDRs had old records attached as required by the SOP, nor did the BDRs contain a notation to indicate the old BDRs could not be located.

Failures to develop, approve, implement and maintain procedures addressing irradiation quality control procedures [21 CFR 606.160(b)(5)]. The inspection revealed that SOP #325, "IRRADIATION OF BLOOD COMPONENTS," does not require the use of indicators for each run to signal product exposure to radiation and our Investigator confirmed that the blood bank does not use irradiation indicators when it irradiates blood and blood components. FDA's guideline "Gamma Irradiation of Blood and Blood Components" that was issued in February 2000, states that an "irradiation indicator should be used with each irradiated batch. There should be procedures for the quality control of the indicator system in use ***."

Equipment used for the irradiation of blood and blood components is not calibrated and maintained in accordance with 21 CFR 606.60(a). Our inspection revealed that the irradiator used by your blood bank failed in February 2000, and the main drive motor and turntable drive required repair. The irradiator was placed back into service on 3/7/00 after daily maintenance was performed and some products were evaluated for radiation exposure. However, dose mapping for those products, was not performed until June 14, 2000.

There are two FDA guidelines that address this issue. The first guideline, dated July 22, 1993, entitled "Recommendations regarding License Amendments and Procedures for Gamma Irradiation of Blood Products" states that "validation studies should be performed to establish the performance of the irradiator within limits," and that "validation should be done annually and after mechanical repairs, especially those involving the sample handling apparatus such as the turntable". The second guideline, the February 2000 guideline referenced above, states "All equipment used in the production of irradiated blood components should be qualified for such use, and ***Qualification should also include measuring the amount of radiation delivered to the products." Following completion of the March 6, 2000 repair to the irradiator, your firm should have performed the dose mapping study then rather than waiting until the regularly scheduled maintenance was performed on June 14, 2000. We do not believe that the actions performed by your firm on the Irradiator on March 7, 2000, meet that requirement. A copy of the February 2000 guideline was given to Dr. Perkins during the inspection.

Failure of Quality Control procedures to include adequate provisions for monitoring the reliability, accuracy, precision and performance of equipment used in the production of irradiated blood components [21 CFR 606 .140(b)]. For example, the current quality control procedures used by your firm require that the timer for the irradiator be synchronized four times annually. Our February 2000 Guideline recommends that the timer should be checked each day of use.

During the discussion with our investigator over the issued FDA 483, item #2 of the FDA 483 was discussed. This citation addressed the fact that your firm's SOP allows verbal review of some of the donor history be waived. Our investigator was asked to identify the FDA Guidelines that address this subject. The only direct reference to oral questioning issued by FDA is our April 23, 1992 guideline titled: "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission of Blood and Blood Products." That guidance recommended the HIV high-risk questions be asked orally. Our belief is that the best way to get the most reliable answers is to ask the questions orally. However, the regulations do not explicitly state that interviews or questions must be presented orally.

Also discussed was item #4 of the FDA 483, that indicates SOP #700 directs staff to process donors as "new" if they deny previous donations at your facility. Neither the current or inactive donor files are checked for these "new" donors. Dr. Perkins asked what FDA guideline requires checking these files for "new donors". There is no FDA guideline that requires this. However, 21 CFR 606.160(b)(1)(vii) requires records to relate the donor to previous donations. A donor simply may not recall having donated previously at your facility and therefore be classified as a "new" donor. We believe that since your firm's procedures require a check of the current and inactive files for previous donors, this procedure should require this check for new donors also.

The above is not intended to be an all-inclusive list of deviations which may exist at your facility. It is your responsibility to ensure that your firm is in full compliance with the Act and all requirements of federal regulations with regard to blood collection, processing, testing and distribution.

You should take prompt action to correct these deviations. Failure to implement corrections may result in regulatory action without further notice.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including supporting documentation, and an explanation of each step being taken to prevent the recurrence of

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similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrective measure will be implemented. Your reply should be sent to the attention of George F. Bailey, Compliance Officer.

Sincerely,

\s\

Raymond V. Mlecko
District Director