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September 24, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-50-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Marisa C. Saint Martin, M.D.
Medical Director
Hinsdale Hospital Blood Bank
120 N. Oak Street
Hinsdale, IL 60521

Dear Dr. Saint Martin:

An inspection of your unlicensed blood bank was conducted from July 9 through 24, 2001. Our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 211 and 600-680 as follows:

Failure to maintain complete and accurate records from which donors may be identified so products from such individuals will not be distributed [21 CFR 606.160(b)(1)]. For example, our investigator reports that of ten permanently deferred donors reviewed in your firm's Central Donor File, four of the donor records were missing.

Failure to follow standard operating procedures for handling post donation information reports [21 CFR 606.100(b)(1)]. For example, donor [REDACTED] donations collected on 1/10/01 and 2/17/01, tested positive for Hepatitis B Core Antibody. Your firm's SOP, entitled "Donor Deferral (HBc)," requires that a donor that tests repeatedly reactive for HBc be permanently deferred. At the conclusion of this inspection, donor [REDACTED] continued to be an eligible donor.

Failure to establish a system that can identify donors who change names, use different names, or report an incorrect date of birth or social security number [21 CFR 606.160(e)].

Failure to validate blood component irradiation procedures [21 CFR 211.100]. No validation studies have been conducted to confirm that a targeted central dose of [REDACTED] and a minimum dose of [REDACTED] at any other point is being delivered for the different configurations used by your firm.

Failure of records that cover the irradiation of blood components to contain information covering each significant step in the processing of the unit [21 CFR 606.160(2)]. For example, the length of time of irradiation is not documented on the Blood Irradiation Log. Also, there are no records that document the quality control procedures used to document the control of the irradiation indicators, such as: storage conditions of the indicators, verification that the indicator has not been exposed to unacceptable temperatures, and an explanation of expected results of each lot (in comparison with the old lot) and corrective action.

At the conclusion of the inspection, an FDA-483, Inspectional Observations, was issued and discussed with you by the investigator. Neither this letter nor the FDA-483 is meant to be an all-inclusive list of deficiencies that may exist at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the regulations.

You should take prompt action to correct these deviations. Failure to implement corrections may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. Please provide the status of these actions in your response. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrective measure will be implemented. Your reply should be sent to the attention of George F. Bailey, Compliance Officer, at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director