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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

January 29, 2001

WARNING LETTER
(corrected)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 30

Larry Moss
President
Interstate Blood Bank, Inc.
3180 Old Getwell Road
Memphis, Tennessee 38118

Dear Mr. Moss:

The Food and Drug Administration (FDA) conducted an inspection of your Interstate Blood Bank, Inc. facility located at 2126 W. Fond du Lac Ave., Milwaukee, WI, from November 28 - 30, 2000.

During the inspection FDA investigators documented violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) and deviations from the applicable standards and requirements of Subchapter F, Parts 600-680, Title 21, Code of Federal Regulations (21 CFR 600-680). The deviations noted on the form FDA-483, Inspectional Observations, issued at the conclusion of the inspection were as follows:

1. Failure to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess in that the skin of the donor at the site of phlebotomy was repeatedly touched by the phlebotomist with an ungloved hand after the site was prepared and no further preparation of the site was conducted prior to venipuncture [21 CFR 640.64(e)].
2. Failure to ensure that the personnel responsible for the collection of blood components have adequate training and experience to assure competent performance of their duties [21 CFR 606.20(b)] in that:
 - a. On November 30, 2000, a trainee phlebotomist was observed repeatedly touching a prepared venipuncture site with an ungloved hand after the site was prepared and no further preparation of the site was conducted prior to venipuncture. No correction of the phlebotomist was attempted

Page Two

Lawrence Moss
January 29, 2001

and a second phlebotomist was required to assist the completion of the venipuncture when the first phlebotomist was unprepared for taping the tubing to the donor's arm.

- b. On November 30, 2000, no trainer was observed providing supervision of a trainee phlebotomist who was permitted to perform phlebotomist duties.
3. Failure to establish adequate written standard operating procedures (SOPs) that include criteria used to determine donor suitability [21 CFR 606.100(b)] in that SOP 0.0015, revision 3(a), does not include all steps to be taken to prevent donors from donating product more than once every two days and no more than twice in a seven day period. For example:
- a. The procedure does the appropriate method for finger staining donors and for checking for finger stains on donors.
 - b. The procedure does not identify corrective action to be taken on a return donor with no stain.
 - c. The procedure does not state the steps to be taken after receipt of "Daily Donor Checks" received from other area donor centers.

Neither this letter nor the form FDA-483, Inspectional Observations, is meant to be an all-inclusive list of deficiencies that may exist at your facility. It is your responsibility as management to ensure that your establishment is in compliance with all requirements of Federal regulations.

You should notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include license suspension, revocation, and/or seizure. Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated on the letterhead.

Sincerely,



David R. Yost
Acting Director
Minneapolis District