



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

297 Plus Park Boulevard
Nashville, TN 37217

June 17, 1998

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Interstate Blood Bank, Inc.
3180 Old Getwell Road
Memphis, TN 38118

ATTN: Joyce V. Clarke
Responsible Head

Warning Letter No. 98-NSV-17

Dear Ms. Clarke:

During an inspection of Interstate Blood Bank, Inc., 64 North Second Street, Memphis, Tennessee, on April 2-3, 6 & 9, 1998, 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, Parts 600-680, as follows:

- Failure to adequately train and/or supervise personnel responsible for the collection of blood, to assure competent performance of their assigned functions and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports and is represented to possess [21 CFR 606.20(b)];
- Failure to adequately determine the suitability of whole blood donors [21 CFR 640.3] in that:
 1. Units of whole blood were collected from donors who did not first furnish a medical history and who did not sign the whole blood donor record cards.
 2. Units of whole blood were collected from donors who presented with elevated temperatures, from donors who were evidently not weighed and/or did not have a hemoglobin or hematocrit determination recorded, from donors who responded to questions in a manner that should have resulted in deferral, and from a donor who had tested positive for syphilis.

- Failure to maintain concurrent, detailed and/or accurate records [21 CFR 606.160(a)] in that:
 1. The phlebotomist was not identified on a number of donor records, and the address of one donor was omitted from the record contrary to your standard operating procedures.

The above violations are not intended to serve as an all-inclusive list of deficiencies at this facility. It remains your responsibility as Responsible Head to assure that your establishment is in compliance with all requirements of the federal regulations.

We acknowledge receipt of your May 4, 1998, response to the FDA Form 483 issued to this facility at the termination of our inspection. It is evident from your response and the reported actions you have already taken that you realize the seriousness of the deviations noted during our inspection. However, only a future reinspection can evaluate the adequacy and permanency of the changes or improvements you implement.

If you care to respond further to these matters, please do so to the attention of Frank J. Jancarek, Compliance Officer, at the above letterhead address.

If you fail to promptly and effectively correct the conditions and practices noted at this facility, it could result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Sincerely,



Raymond K. Hedblad
Director, Nashville District

RKH:FJJ:mrd