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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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Refer to:

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4040

April 17, 1997

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Jack C. Turner, M.D., Medical Director  
Danville Regional Medical Center  
142 S. Main Street  
Danville, Virginia 24541

Dear Dr. Turner:

During a Food and Drug Administration (FDA) inspection of your medical center blood bank located in Danville, Virginia, on March 26-28, 1997, 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 600-680, as follows:

1. Failure to establish scientifically sound and appropriate specifications, standards, and test procedures to assure that blood and blood components are safe, pure, potent, and effective [21 CFR 606.140(a)], in that you released, for transfusion, an unsuitable product. For example, for HbC repeat reactive Unit [REDACTED], drawn on February 26, 1997, the RBC component was transfused and not destroyed along with the other components, Platelets and Salvage Plasma, which were discarded on March 4, 1997.
2. Failure to assure that donors are in good health as indicated by demonstration that the systolic and diastolic blood pressures are within normal limits [21 CFR 640.3(b)(2)]. Donor A.T.A. of Unit # [REDACTED] did not have blood pressure recorded on the donor card.
3. Failure to maintain accurate records from which unsuitable donors may be identified so that products from such individuals will not be distributed [21 CFR 606.160(a)(1) and (b)(1)]:
  - a. Two donors had conflicting Social Security numbers on their donor cards.

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- b. The unit donors' last names for Units #DAN0027958 and #DAN0033735, that were entered in the computer documenting test results and product disposition, differed from the last names entered on the donor cards.

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

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such action includes seizure and/or injunction.

You should 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 and to prevent their recurrence. 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 completed.

Your response should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,



Carl E. Draper  
Acting Director, Baltimore District