



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

D1348 B

November 24, 1997

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

**WARNING LETTER**

CHI-4-98

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Edward C. Farkas, M.D.  
Medical Director  
Danville Elks Blood Bank, Inc.  
300 East Liberty Lane  
Danville, Illinois 61832

Dear Dr. Farkas:

An inspection of the Danville Hospital Blood Bank was conducted from September 9, 1997 through September 30, 1997, by FDA Investigator Roger J. Adams. Investigator Adams documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680, which included:

Failure to ensure that all viral marker tests are conducted according to the manufacturer's test kit instructions, or according to your blood bank's written Standard Operating Procedure. For example:

The [REDACTED] test procedure for the immunoassay test for the qualitative detection of antibody to Human T-Lymphotropic Virus Type 1 (HTLV-1) specifies that the specimen be added first. Investigator Adams observed that what occurs at your facility is that the diluent is added first.

Investigator Adams determined that certain units of blood, [REDACTED], drawn 6/10/97, and [REDACTED], drawn 1/17/97, were found, by enzyme immunoassay (EIA) test, to be repeat reactive for Hepatitis B Surface Antigen (Anti-HBc non-reactive and confirmatory non-neutralizable). Packed red blood cells from both units were released for transfusion, and recovered plasma from unit [REDACTED] was distributed for use.

Failure to ensure that all donors found to be repeatedly reactive for Hepatitis B Surface Antigen (HBsAg) were not temporarily deferred from further donations or re-entered via an appropriate donor re-entry protocol.

Failure to ensure that the phlebotomists at your facility use, at all times, the correct blood collecting techniques.

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Failure to have a written protocol for the invalidation of infectious disease tests.

Failure to document invalid test runs or to document incubation times during infectious disease testing.

This letter, as well as the Form FDA-483, Inspection Observations, issued at the conclusion of the inspection, are not intended to be all inclusive listings of the deficiencies at your facility. It is your responsibility to ensure that all requirements of the Act, and regulations promulgated thereunder, are being met.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, such as injunction, 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 and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason(s) for delay and the time within which the corrections will be completed.

Your reply should be sent to the attention of Richard Harrison, Acting Compliance Officer.

Sincerely,



Raymond V. Mlecko  
District Director

Enclosure

cc: Laboratory Regulation Unit  
Office of Health Care Regulation  
Illinois Department of Public Health  
525 W. Jefferson  
Springfield, IL 62701